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APPLICATION NUMBER: *PCT/US05/00508*

FILING DATE: *January 07, 2005*

RELATED PCT APPLICATION NUMBER: *PCT/US06/00286*

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY
APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS
CONVENTION, IS *USPCT/US05/00508*

By Authority of the
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PCT REQUEST

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Original (for SUBMISSION)

0	For receiving Office use only	
0-1	International Application No.	PCT/US 05/00508
0-2	International Filing Date	07 JAN 2005 (07.01.05)
0-3	Name of receiving Office and "PCT International Application"	PCT INTERNATIONAL APPLICATION FORM
0-4	Form PCT/RO/101 PCT Request	
0-4-1	Prepared Using	PCT-SAFE [EASY mode] Version 3.50 (Build 0002.163)
0-5	Petition The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	Receiving Office (specified by the applicant)	United States Patent and Trademark Office (USPTO) (RO/US)
0-7	Applicant's or agent's file reference	14853-2PCT
I	Title of Invention	DRAIN WITH OCCLUSION REMOVING STRUCTURE
II	Applicant II-1 This person is II-2 Applicant for II-4 Name II-5 Address	applicant only all designated States except US THE CATHETER EXCHANGE, INC. 16633 Ventura Boulevard Suite 735 Encino, California 91436 United States of America
II-6	State of nationality	US
II-7	State of residence	US
III-1	Applicant and/or inventor III-1-1 This person is III-1-2 Applicant for III-1-4 Name (LAST, First) III-1-5 Address	applicant and inventor US only DEUTSCH, Harvey L. 350 Comstock Avenue Los Angeles, California 90024 United States of America
III-1-6	State of nationality	US
III-1-7	State of residence	US

PCT REQUEST

Original (for SUBMISSION)

IV-1	Agent or common representative; or address for correspondence The person identified below is hereby/ has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	agent
IV-1-1	Name (LAST, First)	FARAH, David A.
IV-1-2	Address	SHELDON & MAK PC 225 South Lake Avenue Suite 900 Pasadena, California 91101 United States of America
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IV-1-6	Agent's registration No.	38,134
IV-2	Additional agent(s)	additional agent(s) with same address as first named agent
IV-2-1	Name(s)	SHELDON, Jeffrey G. (27,953); MAK, Danton K. (31,695); ANDERSON, Denton L. (30,153); ROSE, Robert J. (47,037)
V	DESIGNATIONS	
V-1	The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.	
VI-1	Priority claim of earlier national application	
VI-1-1	Filing date	09 January 2004 (09.01.2004)
VI-1-2	Number	60/535,224
VI-1-3	Country	US
VI-2	Priority claim of earlier national application	
VI-2-1	Filing date	19 April 2004 (19.04.2004)
VI-2-2	Number	60/563,597
VI-2-3	Country	US
VI-3	Priority document request The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s):	VI-1, VI-2

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Original (for SUBMISSION)

VII-1	International Searching Authority Chosen	United States Patent and Trademark Office (USPTO) (ISA/US)	
VIII	Declarations	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	-	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	-	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	-	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	-	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	-	
IX	Check list	number of sheets	electronic file(s) attached
IX-1	Request (including declaration sheets)	4	✓
IX-2	Description	22	-
IX-3	Claims	6	-
IX-4	Abstract	1	✓
IX-5	Drawings	8	-
IX-7	TOTAL	41	
IX-8	Accompanying Items	paper document(s) attached	electronic file(s) attached
IX-11	Fee calculation sheet	✓	-
IX-11	Copy of general power of attorney	reference no. 14853-2PCT	-
IX-11	Copy of general power of attorney	reference no. 14853-2PCT	-
IX-17	PCT-SAFE physical media	-	✓
IX-19	Figure of the drawings which should accompany the abstract	Figure 19	
IX-20	Language of filing of the international application	English	
X-1	Signature of applicant, agent or common representative	<i>David Farah</i>	
X-1-1	Name (LAST, First)	FARAH, David A.	
X-1-2	Name of signatory		
X-1-3	Capacity		

PCT REQUEST

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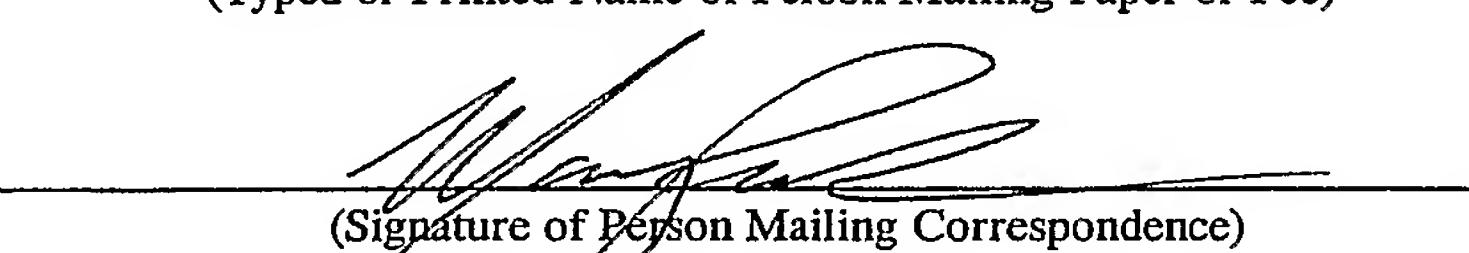
Original (for SUBMISSION)

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10-1	Date of actual receipt of the purported international application	DT02 Rec'd PCT/PTO 07 JAN 2005 (09.01.05)
10-2	Drawings:	
10-2-1	Received	
10-2-2	Not received	
10-3	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application	
10-4	Date of timely receipt of the required corrections under PCT Article 11(2)	
10-5	International Searching Authority	ISA/US
10-6	Transmittal of search copy delayed until search fee is paid	

FOR INTERNATIONAL BUREAU USE ONLY

11-1	Date of receipt of the record copy by the International Bureau	
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CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)		Docket No. 14853-2PCT
International Application No. To be assigned	International Filing Date 7 January 2005	Priority Date Claimed 9 January 2004
Applicant(s): THE CATHETER EXCHANGE, INC.		
Inventor/Applicant(s): DEUTSCH, Harvey L.		
Invention: DRAIN WITH OCCLUSION REMOVING STRUCTURE		
<p>I hereby certify that the following correspondence:</p> <ol style="list-style-type: none"> 1. Transmittal Letter to the United States Receiving Office (1 page) 2. PCT Request (4 pages) 3. PCT (Annex - Fee Calculation Sheet) (1 page) and Abstract of Application (1 page) 4. Patent Application (22 pages Disclosure, 6 pages Claims and 1 page Abstract) 5. 8 Sheets of Drawings (containing Figures 1 through 24) 6. Copy of General Power of Attorney executed by officer of THE CATHETER EXCHANGE, INC. (1 page) 7. Copy of General Power of Attorney executed by inventor Harvey L. DEUTSCH. (1 page) 8. PCT-SAFE Diskette 9. Acknowledgment of Receipt Postcard <p>is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 in an envelope addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on: <u>7 JANUARY 2005</u>.</p> <p>(Date)</p>		
<p style="text-align: right;">Marilyn Paik</p> <p>(Typed or Printed Name of Person Mailing Paper or Fee)</p>  <p>(Signature of Person Mailing Correspondence)</p>		
<p style="text-align: right;">("Express Mail" Mailing Label No. EV 276872935 US)</p>		

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PCT/US2005/00508

GENERAL POWER OF ATTORNEY

(for several international applications filed under the Patent Cooperation Treaty)

(PCT Rule 90.5)

The undersigned person(s) :

(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

THE CATHETER EXCHANGE, INC.
16633 Ventura Boulevard
Suite 735
Encino, California 91436
United States of America

hereby appoint(s) the following person as:

agent

common representative

Name and address

(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

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Sheldon & Mak PC
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Tel.: (626) 796-4000
Fax: (626) 795-6321

to represent the undersigned before

all the competent International Authorities

the International Searching Authority only

the International Preliminary Examining Authority only

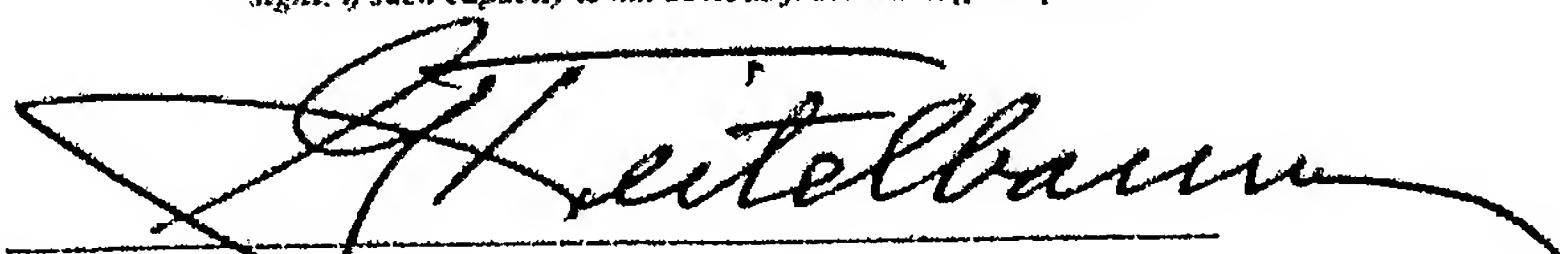
in connection with any and all international applications filed by the undersigned with the following Office

US

as receiving Office

and to make or receive payments on behalf of the undersigned.

Signature(s) (where there are several persons, each of them must sign; next to each signature, indicate the name of the person signing and the capacity in which the person signs, if such capacity is not obvious from reading this power):



George P. Teitelbaum
Chief Executive Officer
THE CATHETER EXCHANGE, INC.

Date:

1/6/05

PCT

GENERAL POWER OF ATTORNEY (for several international applications filed under the Patent Cooperation Treaty) (PCT Rule 90.5)

The undersigned person(s):
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

DEUTSCH, Harvey L.
350 Comstock Avenue
Los Angeles, California 90024
United States of America

hereby appoint(s) the following person as:

agent common representative

Name and address
(Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

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Sheldon & Mak PC
225 South Lake Avenue
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United States of America
Tel.: (626) 795-4000
Fax: (626) 795-6321

to represent the undersigned before

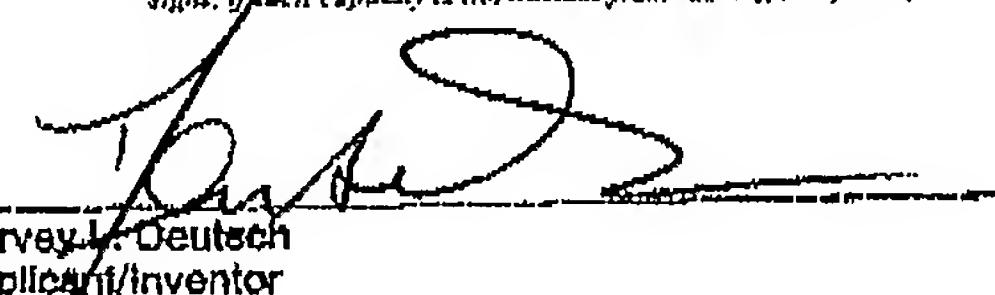
all the competent International Authorities
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In connection with any and all international applications filed by the undersigned with the following Office

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and to make or receive payments on behalf of the undersigned.

Signature(s) (where there are several persons, each of them must add his/her signature. Indicate the name of the person signing and the capacity in which he signs, if such capacity is not obvious from reading this power).


Harvey L. Deutsch
Applicant/inventor

Date: 1/6/05

PCT (ANNEX - FEE CALCULATION SHEET)

Original (for SUBMISSION)

(This sheet is not part of and does not count as a sheet of the international application)

0	For receiving Office use only			
0-1	International Application No.	PCT/US 05/00508		
0-2	Date stamp of the receiving Office	RO/US 07 JAN 2005 (07.01.05)		
0-4	Form PCT/RO/101 (Annex) PCT Fee Calculation Sheet			
0-4-1	Prepared Using	PCT-SAFE [EASY mode] Version 3.50 (Build 0002.163)		
0-9	Applicant's or agent's file reference	14853-2PCT		
2	Applicant	THE CATHETER EXCHANGE, INC.		
12	Calculation of prescribed fees	fee amount/multiplier	Total amounts (USD)	
12-1	Transmittal fee T	⇒	300	300
12-2-1	Search fee S	⇒	1000	1000
12-2-2	International search to be carried out by US			
12-3	International filing fee (first 30 sheets) i1	1134		1134
12-4	Remaining sheets	11		
12-5	Additional amount (X)	12		132
12-6	Total additional amount i2	132		
12-7	i1 + i2 = I	1266		1266
12-12	EASY Filing reduction R	-81		81-
12-13	Total International filing fee (i-R) I	⇒	1185	1185
12-14	Fee for priority document Number of priority documents requested	2		
12-15	Fee per document (X)	20		
12-16	Total priority document fee: P	⇒	40	40
12-17	TOTAL FEES PAYABLE (T+S+I+P)	⇒	2525	\$ 2525.00
12-19	Mode of payment	authorization to charge deposit account		
12-20	Deposit account instructions The receiving Office	United States Patent and Trademark Office (USPTO) (RO/US)		
12-20-1	Authorization to charge the total fees indicated above	✓		
12-20-2	Authorization to charge any deficiency or credit any overpayment in the total fees indicated above	✓		
12-20-3	Authorization to charge the fee for priority document	✓		
12-21	Deposit account No.	19-2090		
12-22	Date	07 January 2005 (07.01.2005)		
12-23	Name and signature	FARAH, David A. <i>David Farah</i>		

DRAIN WITH OCCLUSION REMOVING STRUCTURE

CROSS-REFERENCE TO RELATED APPLICATIONS

The present Application claims the benefit of United States Provisional Patent Application 60/535,224 titled "Drain with Occlusion removing structure," filed January 9, 2004; and claims the benefit of United States Provisional Patent Application 60/563,597 5 titled "Drain with Occlusion removing structure," filed April 19, 2004; the contents of which are incorporated in this disclosure by reference in their entirety.

BACKGROUND

There are a variety of medical drains, such as Penrose and Jackson-Pratt drains, used post-operatively to control blood and serosanguinous discharge from operative sites 10 and wounds. Drains are typically used following major open abdominal operations, as well as during operations involving the back, spine, breast, head and hip. Drains help prevent the accumulation of hematomas and seromas in post-operative sites that lead to infections, abscesses, poor wound healing and wound dehiscence.

Medical drains generally have a distal end that is placed in the surgical site and a 15 proximal end that is brought through the skin through a stab incision adjacent to the closed surgical incision. The proximal end of the drain is usually secured to the skin by one or more sutures.

Further, the proximal end of the drain is typically connected to a suction device, such as a compressible egg-shaped, container or bulb (a "hand grenade"). Connecting the 20 suction device to the drain applies negative pressure through the drain and into the surgical site, encouraging the egress of fluid from the surgical site through the drain. The suction device is emptied of drainage fluid, and the amount of drainage is measured periodically, such as per nursing shift or per day. The drain is removed when the amount of drainage diminishes below a set amount during a specific time.

Disadvantageously, however, medical drains are prone to occlusion with inspissated 25 bloody or serosanguinous drainage, allowing fluids to collect at the surgical site. When a drain occludes, it must be replaced, either by an open surgical procedure or by a minimally

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invasive surgical procedure, such as for example a procedure involving interventional radiology. Drain replacement procedures add significant extra expense and increase the risk of patient morbidity during the patient's post-operative course.

Therefore, there is a need for a new device or method that addresses the issue of
5 occluded drains that involves less expense or less risk to the patient.

SUMMARY

According to one embodiment of the present invention, there is provided a drainage device comprising means for drainage and means for removing an occlusion. According to another embodiment of the present invention, there is provided a method of unoccluding a
10 means for drainage. The method comprises a) providing the drainage device; b) placing the drainage device into an area to be drained; c) allowing occluding material to occlude the means for drainage; and d) removing the means for removing an occlusion from the means for drainage, thereby unoccluding the means for drainage.

According to another embodiment of the present invention, there is provided a
15 drainage device. The device comprises a drain comprising a proximal end, a distal end and a central lumen; and an occlusion removing structure within the central lumen comprising a proximal end and a distal end. The proximal end of the drain comprises an adaptor configured to mate with a suction device, the distal end of the drain comprises one or more than one aperture, the occlusion removing structure comprises one or more than one tubular structure comprising a wall, and the distal end of the occlusion removing structure comprises one or more than one aperture. In one embodiment, the drainage device further comprises a suction device mated with the adapter. In another embodiment, the occlusion removing structure comprises a plurality of co-axial tubular structures. In another
20 embodiment, the number of the one or more than one aperture on the distal end of the drain is equal to the number of the one or more than one aperture on the distal end of the occlusion removing structure. In another embodiment, the proximal end of the occlusion removing structure comprises an appendage. In another embodiment, the appendage comprises an identification tag. In another embodiment, the proximal end of the drain comprises a cap. In another embodiment, the occlusion removing structure comprises an
25

outer surface, the drain comprises an inner surface, and where the outer surface of the occlusion removing structure, or the inner surface of the drain, or both have a lubricious coating. In another embodiment, the drain further comprises one or more than one structure for securing the proximal end of the device. In another embodiment, the wall 5 comprises a snare. In another embodiment, the occlusion removing structure is a first occlusion removing structure, and where the device further comprises a second occlusion removing structure comprising a proximal end, a distal end, an intermediate segment between the proximal end and the distal end, and an inflation balloon on the distal end.

According to another embodiment of the present invention, there is provided a 10 method of unoccluding a drainage device. The method comprises a) providing the drainage device of according to the present invention; b) placing the distal end of the drain into an area to be drained; c) allowing occluding material to occlude the drain; and d) removing the occlusion removing structure from the drain, thereby unoccluding the drain. In one embodiment, the method further comprises attaching the drainage device to a suction device 15 after placing the distal end of the drain. In another embodiment, the method further comprises reattaching the drainage device to the suction device after removing the occluding material removing structure. In another embodiment, the occlusion removing structure comprises an appendage, and removing the occlusion removing structure comprises applying proximal traction to the appendage, thereby translating the occlusion 20 removing structure proximally. In another embodiment, the drain comprises a cap, and removing the occlusion removing structure comprises opening the cap to permit the occlusion removing structure to be removed from the drain. In another embodiment, the occlusion removing structure comprises a plurality of co-axial tubular structures, and removing the occlusion removing structure preferably comprises removing only one of the 25 plurality of co-axial tubular structures. In another embodiment, the method further comprises infusing a fluid between each of the plurality of co-axial tubular structures to facilitate separation of the co-axial structures from each other. In another embodiment, the wall comprises a snare, and removing the occlusion removing structure comprises applying proximal traction to the proximal end of the snare causing the distal end of the occlusion

removing structure to contract in a purse-string type fashion, thereby substantially or completely sealing the distal end of the occlusion removing structure.

According to another embodiment of the present invention, there is provided a drainage device. The device comprises a drain comprising a proximal end, a distal end and a central lumen, and an occlusion removing structure within the central lumen comprises a proximal end and a distal end. The proximal end of the drain comprises an adaptor configured to mate with a suction device, the distal end of the drain comprises one or more than one aperture, and the occlusion removing structure comprises a tubular mesh. In one embodiment, the proximal end of the occlusion removing structure comprises a plurality of loops. In another embodiment, the drainage device further comprises a suction device mated with the adapter. In another embodiment, the proximal end of the occlusion removing structure comprises an appendage. In another embodiment, the proximal end of the drain comprises a cap. In another embodiment, the drain further comprises one or more than one structure for securing the proximal end of the device. In another embodiment, the occlusion removing structure comprises a connector on the proximal end. In another embodiment, the device further comprises a joint between the adaptor and the connector, and further comprises a sealant for sealing the joint between the connector and the adaptor. In another embodiment, the occlusion removing structure is a first occlusion removing structure, and where the device further comprises a second occlusion removing structure comprising a proximal end, a distal end, an intermediate segment between the proximal end and the distal end, and an inflation balloon on the distal end.

According to another embodiment of the present invention, there is provided a method of unoccluding a drainage device. The method comprises a) providing the drainage device of claim 22; b) placing the distal end of the drain into an area to be drained; c) allowing occluding material to occlude the drain; and d) removing the occlusion removing structure from the drain, thereby unoccluding the drain. In one embodiment, the method further comprises attaching the drainage device to a suction device after placing the distal end of the drain. In another embodiment, the method further comprises reattaching the drainage device to the suction device after removing the occluding material removing

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structure. In another embodiment, the method where the occlusion removing structure comprises an appendage, and where removing the occlusion removing structure comprises applying proximal traction to the appendage, thereby translating the occlusion removing structure proximally. In another embodiment, the method where the drain comprises a cap, 5 and where removing the occlusion removing structure comprises opening the cap to permit the occlusion removing structure to be removed from the drain. In another embodiment, the method where the proximal end of the occlusion removing structure comprises loops, and where removing the occlusion removing structure from the drain comprises pulling the proximal end of the occlusion removing structure into a sheath. In another embodiment, 10 the method further comprises replacing the occlusion removing structure in the drain after unoccluding the drain. In another embodiment, replacing the occlusion removing structure in the drain after unoccluding the drain comprises advancing an introducer containing the replacement occlusion removing structure through the proximal end of the drain until the distal end of the replacement occlusion removing structure is placed at or near the distal 15 end of the drain, and then removing the introducer leaving the replacement occlusion removing structure within the drain.

According to another embodiment of the present invention, there is provided a drainage device. The device comprises a drain comprising a proximal end, a distal end and a central lumen, and b) an occlusion removing structure within the central lumen comprises 20 a proximal end, a distal end and intermediate segment between the proximal end and the distal end. The proximal end of the drain comprises an adaptor configured to mate with a suction device, the distal end of the drain comprises one or more than one aperture, and the occlusion removing structure comprises an inflation balloon on the distal end. In one embodiment, the drain further comprises a suction device mated with the adapter. In 25 another embodiment, the proximal end of the drain comprises a cap. In another embodiment, the drain further comprises one or more than one structure for securing the proximal end of the device. In another embodiment, the drain further comprises a collapsible sleeve.

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According to another embodiment of the present invention, there is provided a method of unoccluding a drainage device comprising a) providing the drainage device according to the present invention; b) placing the distal end of the drain into an area to be drained; c) allowing occluding material to occlude the drain; d) inflating the inflatable balloon; and e) removing the occlusion removing structure from the drain, thereby unoccluding the drain. In one embodiment, the method further comprises attaching the drainage device to a suction device after placing the distal end of the drain. In another embodiment, the method further comprises reattaching the drainage device to the suction device after removing the occluding material removing structure. In another embodiment, the drain comprises a cap, and removing the occlusion removing structure comprises opening the cap to permit the occlusion removing structure to be removed from the drain. In another embodiment, the method further comprises replacing the occlusion removing structure in the drain after unoccluding the drain. In another embodiment, the method further comprises replacing the occlusion removing structure in the drain after unoccluding the drain. In another embodiment, the drain further comprises a collapsible sleeve, and the collapsible sleeve is extended proximally as the occlusion removing structure is removed from the drain.

FIGURES

These and other features, aspects and advantages of the present invention will become better understood with regard to the following description, appended claims, and accompanying figures where:

Figure 1 is a partial, lateral perspective view of one embodiment of a drainage device according to the present invention comprising a drain with an occlusion removing structure, shown with a suction device attached;

Figure 2 is a partial, cutaway, lateral perspective view of the embodiment of the device shown in Figure 1;

Figure 3 is a partial, cutaway, lateral perspective view of another embodiment of a drainage device shown in Figure 1, with an alternate embodiment of the occlusion removing structure;

Figure 4 is a cross-sectional view of the device shown in Figure 3, taken along line 4-4;

Figure 5 is a close-up view of the distal end of the occlusion removing structure of one embodiment of the drainage device shown in Figure 1 comprising a snare with the 5 snare open;

Figure 6 is another close-up view of the distal end of the occlusion removing structure of one embodiment of the drainage device shown in Figure 1 comprising a snare with the snare closed;

Figure 7 is another partial, cutaway, lateral perspective view of the embodiment of 10 the device shown in Figure 1 showing an occlusion being removed from the device according to the method of the present invention;

Figure 8 is a partial, cutaway, lateral perspective view of another embodiment of a drainage device shown in Figure 1;

Figure 9 is a partial, lateral perspective view of an alternate embodiment of the 15 occlusion removing structure shown as part of the drainage device shown in Figure 8;

Figure 10 through Figure 12 show various steps in a method of unoccluding an occluded drain according to the present invention, using the drainage device shown in Figure 8;

Figure 13 is a lateral perspective view of an introducer with a replacement occlusion 20 removing structure within the introducer according to the present invention;

Figure 14 is a bottom perspective view of the introducer with a replacement occlusion removing structure within the introducer shown in Figure 13;

Figure 15 is a partial, cutaway, lateral perspective view of a device according to the 25 present invention having the replacement occlusion removing structure inserted into the device;

Figure 16 is another partial, cutaway, lateral perspective view of a device according to the present invention having the replacement occlusion removing structure inserted into the device;

Figure 17 is a partial, lateral perspective view of an embodiment of an occlusion removing structure for use in a device according to the present invention;

5 Figure 18 is a partial, cutaway, lateral perspective view of another embodiment of a drainage device according to the present invention comprising the occlusion removing structure shown in Figure 17;

Figure 19 is a partial cutaway, lateral perspective view of a drainage device shown in Figure 18 connected to a suction device, and with the distal end of the device within a drainage area;

10 Figure 20 is a partial cutaway, lateral perspective view of a drainage device shown in Figure 18 connected to a suction device, showing material occluding the central lumen of the drain;

Figure 21 is a partial cutaway, lateral perspective view of a drainage device shown in Figure 18 showing the occluding material being removed from the drain with an occlusion removing structure;

15 Figure 22 is a partial, cutaway, lateral perspective view of another embodiment of a drainage device according to the present invention comprising a drain with an occlusion removing structure;

Figure 23 is another partial, cutaway, lateral perspective view of the embodiment of the device shown in Figure 22 showing an occlusion being removed from the device according to the method of the present invention; and

20 Figure 24 is another partial, cutaway, lateral perspective view of the embodiment of the device shown in Figure 22 showing an occlusion being removed from the device according to the method of the present invention.

DESCRIPTION

25 According to one embodiment of the present invention, there is provided a drainage device comprising an occlusion removing structure. According to another embodiment of the present invention, there is provided a method of unoccluding an occluded drain. In a preferred embodiment, the method comprises providing a device according to the present invention. The device and method prolongs the useful life of a drain, such as a medical

drain, and obviate the need for replacing the drain when it becomes occluded, thereby decreasing the cost associated with drain replacement, and the risk of patient morbidity associated with drain replacement. Though the drainage device of the present invention is presented primarily in the context of a medical drain in this disclosure, the drainage device
5 can also be used for other non-surgical purposes, as will be understood by those with skill in the art with reference to this disclosure.

The device and method will now be presented in detail.

As used in this disclosure, the term "comprise" and variations of the term, such as "comprising" and "comprises," are not intended to exclude other additives, components,
10 integers or steps.

As used in this disclosure, the term "occlude" and variations of the term, such as "occluded," "occluding," and "occlusion" means a mass or clog of occluding material within the central lumen of a drain, which either partially or completely decreases the function of a drain.

15 All dimensions specified in this disclosure are by way of example only and are not intended to be limiting. Further, the proportions shown in these Figures are not necessarily to scale. As will be understood by those with skill in the art with reference to this disclosure, the actual dimensions of any device or part of a device disclosed in this disclosure will be determined by its intended use.

20 The devices of the present invention and their component parts comprise any suitable material for the intended purpose of the device, as will be understood by those with skill in the art with reference to this disclosure. For example, when used as a medical drain, the device will usually comprise one or more than one biocompatible material capable of being sterilized, and the drain portion of the device will preferably comprise material that can be easily cut to a desired length as appropriate for the intended use. By
25 way of example only, in one embodiment when the device is used as a medical drain, the drain portion of the device has an outer diameter of between about 3 and about 10 mm (9-30 French).

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As will be understood by those with skill in the art with reference to this disclosure, the device of the present invention can be used for a variety of both surgical and non-surgical uses. Examples of surgical uses include biliary tubes and stents, chest tubes, decompression catheters, feeding tubes, gastrointestinal decompression catheters, 5 gastrostomy tubes, jejunostomy tubes, mediastinal tubes, nasogastric tubes, nephrostomy catheters, percutaneous drainage catheters, peritoneal dialysis catheters such as abscess drainage catheters, vascular catheters such as venous hemodialysis catheters, and ventriculostomy tubes. Further, the device of the present invention can be used as biliary and urinary drainage catheters, such as Foley-type bladder catheters placed after bloody surgeries, such as prostate resections, where drain tubes particularly tend to occlude with blood clots. Additionally, the device of the present invention can be utilized as a sump-type tube, that is, a drain possessing an additional lumen used to draw external air into the patient while suction is applied to the drain to prevent adhesion of the drain's side apertures to the surrounding tissues within the wound or body cavity, thereby preventing fluid 10 drainage through the drain. Therefore, as will be understood by those with skill in the art with reference to this disclosure, though the present invention is disclosed in terms of a "drainage device" comprising a "drain," neither the device nor the method of use are intended to be limited to draining only, but encompass any other use as appropriate for the structure.

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In one embodiment, the present invention comprises a drainage device. The drainage device comprises means for drainage and means for removing an occlusion. In each of the embodiments of the drainage device disclosed, the means for drainage and the means for removing an occlusion will be identified or will be understood by those with skill in the art with reference to this disclosure. In general, the means for removing an 20 occlusion is the occlusion removing structure referred to in this disclosure, and the means for drainage is the remainder of the device.

25

Referring now to Figure 1 through Figure 7, there are shown, respectively, a partial, lateral perspective view of one embodiment of a drainage device according to the present invention comprising a drain with an occlusion removing structure, shown with a

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suction device attached (Figure 1); a partial, cutaway, lateral perspective view of the embodiment of the device shown in Figure 1 (Figure 2); a partial, cutaway, lateral perspective view of another embodiment of a drainage device shown in Figure 1, with an alternate embodiment of the occlusion removing structure (Figure 3); a cross-sectional view 5 of the device shown in Figure 3, taken along line 4-4 (Figure 4); a close-up view of the distal end of the occlusion removing structure of one embodiment of the drainage device shown in Figure 1 comprising a snare with the snare open (Figure 5); another close-up view of the distal end of the occlusion removing structure of one embodiment of the drainage device shown in Figure 1 comprising a snare with the snare closed (Figure 6); 10 another partial, cutaway, lateral perspective view of the embodiment of the device shown in Figure 1 showing an occlusion being removed from the device according to the method of the present invention (Figure 7).

As can be seen, in one embodiment of the present invention, the drainage device 100 comprises a drain 102 comprising a proximal end 104, a distal end 106 and a central 15 lumen 108. In a preferred embodiment, the proximal end 104 of the drain 102 comprises an adaptor 110 configured to mate with a suction device 112. The adaptor 110 can comprise a side-arm connecting tube, as shown in Figure 1, or can be configured to mate with a suction device through the proximal-most opening of the adaptor 110, or can be configured to mate with a suction device in another manner, as will be understood by those 20 with skill in the art with reference to this disclosure. In a particularly preferred embodiment, such as when the device 100 is being used as a medical drain, the suction device 112 is a bulb-type suction device as shown in Figure 1; however, the suction device 112 can be any suitable suction device, as will be understood by those with skill in the art with reference to this disclosure. In a particularly preferred embodiment, the device 100 25 itself further comprises a suction device 112 configured to mate with the adapter 110. The suction device 112 can be any suitable suction device as will be understood by those with skill in the art with reference to this disclosure, such as for example a bulb-type suction device as shown in Figure 1.

The distal end 112 of the drain 102 comprises one or more than one aperture 114 extending through the wall of the drain 102 from the central lumen 108 to the exterior of the drain 102. In one embodiment, one of the apertures 114 on the distal end 106 of the drain 102 is at the distal-most end of the distal end 106 of the drain, as shown in Figure 1, 5 Figure 2, Figure 3 and Figure 7.

The drainage device 100 further comprises an occlusion removing structure 116. The occlusion removing structure 116 comprises one or more than one tubular structure configured to fit within the central lumen 108 of the drain 102. In one embodiment, as shown in Figure 2, the occlusion removing structure 116 comprises only one tubular structure. In a preferred embodiment, as shown in Figure 3 and Figure 4, the occlusion removing structure 116 comprises a plurality of co-axial tubular structures configured to fit within the central lumen 108 of the drain 102. The occlusion removing structure 116 comprises a proximal end 118 and a distal end 120. The distal end 120 of the occlusion removing structure 116 comprises one or more than one aperture 122 extending through the wall of the occlusion removing structure 116. In a preferred embodiment, the apertures 114 and 122 are arranged such that, when the occlusion removing structure 116 is placed within the drain 102, the apertures 114 and 122 align, permitting drainage to enter the central lumen 108 of the drain 102 from the drainage area surrounding the distal end 106 of the drain 102 of the device 100. In a particularly preferred embodiment, the number of 10 apertures 114 on the distal end 106 of the drain 102 equal the number of apertures 122 on the distal end 120 of the occlusion removing structure 116. One of the apertures 122 on the distal end 120 of the occlusion removing structure 116 can be at the distal-most end of the distal end 120 of the occlusion removing structure 116, as shown in Figure 2, Figure 3 and 15 Figure 7.

In a preferred embodiment, as shown in Figure 1 through Figure 4, the proximal 20 end 118 of the occlusion removing structure 116 comprises an appendage 124. In the embodiment shown in Figure 3, when the occlusion removing structure 116 comprises a plurality of co-axial tubular structures, each tubular structure preferably comprises a separate appendage 124. The appendage 124 is configured to permit an operator to remove

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the occlusion removing structure 116 from of the drain 102, as shown in Figure 2, or to remove one of the co-axial tubular structures, as shown in Figure 3, by applying proximal traction on the appendage 124. In one embodiment, as shown, the appendage 124 comprises a long, thin strip of material, with or without an expanded end or loop at the proximal-most end, or comprises a gathering of the material that comprises the occlusion removing structure 116. The appendage 124, when present, is configured to extend proximally through the adaptor 108 when present, or through a valve in the adaptor 108, as shown in Figure 1, Figure 2 and Figure 3. When the occlusion removing structure 116 comprises a plurality of co-axial tubular structures, and each structure preferably comprises a separate appendage 124, each appendage 124 preferably comprises a separate identification tag 126 to assist the operator in selecting the proper appendage 124 attached to each of the plurality of co-axial tubular structures to apply proximal traction to the tubular structure.

In another preferred embodiment, the drain 102 further comprises a cap 128 that prevents contamination through the proximal end 104 of the drain 102 during use. In a particularly preferred embodiment, the cap 128 is a resealable, snap-open type cap as shown in Figure 1, Figure 2, Figure 3 and Figure 7, and can comprise a valve within the cap 128. The cap 128 can, however, be any structure suitable for the purpose, as will be understood by those with skill in the art with reference to this disclosure, such as for example, a screw-on cover. When the cap 128 is in the closed position, as shown in Figure 1 and Figure 3, the cap 128 engages the proximal end of each appendage 124 present preventing movement of the appendage 124, as well as preventing contamination through the proximal end 104 of the drain 102. When the cap 128 is in the open position, as shown in Figure 2, however, the occlusion removing structure 116 can be translated proximally out of the drain 102, as shown in Figure 7, by applying proximal traction on the appendage 124. In another preferred embodiment, either the outer surface of the occlusion removing structure 116, or the inner surface of the drain 102, or both have a lubricious coating to aid in separation of the occlusion removing structure 116 from the drain 102 during proximal translation of the occlusion removing structure 116. In another embodiment, the drain 102

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comprises one or more than one structure 130 for securing the proximal end 104 of the device 100, such as one or more than one loop, as shown, for securing the proximal end of the device 100 to the skin of a patient, when the device 100 is used as a medical drain, or to another structure, when the device 100 is used as a non-medical drain.

5 Referring now to Figure 5 through Figure 7, in another preferred embodiment, the occlusion removing structure 116 comprises a snare 132 embedded in the wall of the occlusion removing structure 116. When present, applying proximal traction to the proximal end of the snare 132, which can be the appendage 124, causes the distal end 120 of the occlusion removing structure 116 to contract in a purse-string type fashion, thereby substantially or completely sealing the distal end 120 of the occlusion removing structure 116, and preventing any occluding material present in the occlusion removing structure 116 to remain in the occlusion removing structure 116 during removal of the occlusion removing structure 116 from the drain 102. When the occlusion removing structure 116 comprises a plurality of co-axial tubular structures, as shown in Figure 3 and Figure 4, 10 each co-axial tubular structure preferably comprises a separate snare 132.

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In another embodiment, the present invention comprises a method of unoccluding an occluded drain. The method comprises, first, providing a drainage device 100 according to the present invention, such as the device shown in Figure 1 through Figure 7. Next, the distal end 106 of the drain 102 is placed within an area to be drained and allowed to drain 20 drainage for the area. Then, after the central lumen 108 of the drain 102 is occluded with an occluding material 134, the occlusion removing structure 116 is removed from the drain 102 by applying proximal traction to the proximal end 118 of the occlusion removing structure 116, thereby removing the occluding material 134 within the occlusion removing structure 116. In one embodiment, the method comprises attaching the device 100 to a 25 suction device 112 after placing the distal end 112 of the drain 102. In another embodiment, the method comprises reattaching the device 100 to the suction device 112 after removing the occluding material 134 removing structure 116. As will be understood by those with skill in the art with reference to this disclosure, when the occlusion removing structure 116 comprises an appendage 124, removing the occlusion removing structure 116

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comprises applying proximal traction to the appendage 124, thereby translating the occlusion removing structure 116 proximally. Further, as will be understood by those with skill in the art with reference to this disclosure, when the drain 102 comprises a cap 128, removing the occlusion removing structure 116 comprises opening the cap 128 to permit the occlusion removing structure 116 to be removed from the drain 102. Additionally, when the occlusion removing structure 116 comprises a plurality of co-axial tubular structures, as shown in Figure 3 and Figure 4, removing the occlusion removing structure 116 preferably comprises removing only one of the plurality of co-axial tubular structures, and the method can optionally comprise infusing a fluid, such as saline, between the separate co-axial tubular structures to facilitate separation of the co-axial structures from each other. Further, when the occlusion removing structure 116 comprises a snare 132, removing the occlusion removing structure 116 comprises applying proximal traction to the proximal end of the snare 132 causing the distal end 120 of the occlusion removing structure 116 to contract in a purse-string type fashion, thereby substantially or completely sealing the distal end of the occlusion removing structure 116, and preventing any occluding material 134 present in the occlusion removing structure 116 to remain in the occlusion removing structure 116 during removal of the occlusion removing structure 116 from the drain 102. When the occlusion removing structure 116 comprises a plurality of co-axial tubular structures, as shown in Figure 3 and Figure 4, each co-axial tubular structure comprises a separate snare 132.

Referring now to Figure 8, there is shown a partial, cutaway, lateral perspective view of another embodiment of a drainage device according to the present invention. As can be seen, the device 100 comprises a drain 102, as disclosed above, and an occlusion removing structure 136. In this embodiment, the occlusion removing structure 136 comprises a proximal end 138 and a distal end 140. The occlusion removing structure 136 is configured to extend substantially throughout the length of the drain 102, with the proximal end 138 of the occlusion removing structure 136 extending through the proximal end of the drain 104, and through the cap 128, when present, as an appendage 124. The occlusion removing structure 136 comprises a tubular mesh and, when used as a medical

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drain, preferably comprises a self-expanding, flexible, kink-resistant, biocompatible mesh material, such as for example, as ELGILOY®, nitinol, stainless steel, or a biocompatible plastic or shape-memory plastic polymer. In one embodiment, when the device 100 is being used as a medical drain, the occlusion removing structure 136 comprises, for
5 example, between about 12 and about 20 braided wires, each wire having a diameter of between about 0.1 mm and 0.15 mm. In another preferred embodiment, the wires comprise an anti-thrombogenic coating. In another preferred embodiment, the occlusion removing structure 136 comprises material that can be easily cut to a desired size. As will be understood by those with skill in the art with reference to this disclosure, when the
10 occlusion removing structure 136 is in place within the drain 102, as shown in Figure 8, the plurality of apertures 142 in the mess structure of the occlusion removing structure 136 permits drainage to enter the central lumen 108 of the drain 102 from the drainage area surrounding the distal end 106 of the drain 102 of the device 100. Referring now to Figure 9, there is shown a partial, lateral perspective view of an alternate embodiment of the
15 occlusion removing structure 136, where the proximal end 138 of the occlusion removing structure 136 comprises a plurality of loops 144.

In another embodiment, the present invention comprises a method of unoccluding an occluded drain. Referring now to Figure 10 through Figure 12, there are shown various steps in a method of unoccluding an occluded drain according to the present invention,
20 using the drainage device shown in Figure 8. As can be seen, the method comprises, first, providing a drainage device 100 according to the present invention, such as the device shown in Figure 8. Then, the distal end 106 of the drain 102 is placed within an area to be drained and allowed to drain drainage from the area. Next, after the central lumen 108 of the drain 102 is occluded with an occluding material 134, as shown in Figure 10, the
25 occlusion removing structure 136 is removed from the drain 102 by applying proximal traction to the proximal end 118 of the occlusion removing structure 136, as shown in Figure 11, thereby removing the occluding material 134 within the occlusion removing structure 136 and unoccluding the drain 102. As proximal traction is applied to the occlusion removing structure 136, the distal end 140 elongates, thereby constricting the

tubular mesh around any occluding material 134 within the central lumen 108 of the drain 102 and assisting in removing the occluding material 134.

In one embodiment, the method comprises attaching the device 100 to a suction device 112 after placing the distal end 112 of the drain 102. In another embodiment, the 5 method comprises reattaching the device 100 to the suction device 112 after removing the occlusion removing structure 136. As will be understood by those with skill in the art with reference to this disclosure, when the occlusion removing structure 136 comprises an appendage 124, removing the occlusion removing structure 136 can comprise applying proximal traction to the appendage 124, thereby translating the occlusion removing 10 structure 136 proximally. Further, as will be understood by those with skill in the art with reference to this disclosure, when drain 102 comprises a cap 128, removing the occlusion removing structure 136 comprises opening the cap 128 to permit the occlusion removing structure 136 to be removed from the drain 102. In another embodiment of the method, the 15 occlusion removing structure 136 is removed by grasping the loops 144 at the proximal end 138 of the embodiment of the occlusion removing structure 136 shown in Figure 9 by a hook and pulling the proximal end 138 into a sheath (not shown).

In a preferred embodiment, the method comprises replacing the occlusion removing structure 136 in the drain 102 after unoccluding the drain 102. Referring now to Figure 13 through Figure 16, there are shown various structures and steps used in replacing the 20 occlusion removing structure 136 in the drain 102 after unoccluding the drain 102, where Figure 13 shows a lateral perspective view of an introducer 146 with a replacement occlusion removing structure 136 within the introducer 146; Figure 14 shows a bottom perspective view of an introducer 146 with a replacement occlusion removing structure 136 within the introducer 146; Figure 15 shows a partial, cutaway, lateral perspective view of a 25 device 100 having the replacement occlusion removing structure 136 inserted into the device 100; and Figure 16 shows another partial, cutaway, lateral perspective view of a device 100 having the replacement occlusion removing structure 136 inserted into the device 100. As can be seen, in one embodiment, the replacement occlusion removing structure 136 is contained in an introducer 146, such as a metal or plastic tube, as shown in

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Figure 13 and Figure 14. The step of replacing the occlusion removing structure 136 in the drain 102 after unoccluding the drain 102 comprises advancing the introducer 146 containing the replacement occlusion removing structure 136 through the proximal end 104 of the unoccluded drain 102 until the distal end 140 of the replacement occlusion removing structure 136 is placed at or near the distal end 106 of the drain 102. Then, the introducer 146 is removed from the drain 102, leaving the replacement occlusion removing structure 136 within the drain 102. Next, the drain 102 is reattached to a suction device 112 as necessary. In a preferred embodiment, the introducer 146 comprises flexible material to allow the introducer 146 containing the replacement occlusion removing structure 136 to negotiate bends or curves in the drain 102. In another preferred embodiment, the distal end 148 of the introducer 146 is blunted to prevent the distal end 148 of the introducer 146 from becoming impacted in apertures 114 in the distal end 106 of the drain 102.

Referring now to Figure 17 and Figure 18, there is shown a partial, lateral perspective view of an embodiment of an occlusion removing structure for use in a device according to the present invention (Figure 17); and a partial, cutaway, lateral perspective view of another embodiment of a drainage device according to the present invention comprising the occlusion removing structure shown in Figure 17 (Figure 18). As can be seen, the occlusion removing structure 150 comprises a proximal end 152 and a distal end 154. The distal end 154 corresponds to the distal end 140 of the occlusion removing structure 136, disclosed in this disclosure. The proximal end 152, however, comprises a connector 156. In a preferred embodiment, as shown in Figure 17 and Figure 18, the connector 156 is a stepped, male connector, (a "Christmas Tree" type connector) capable of mating to a plurality of sizes of female connectors. In a preferred embodiment, the adaptor 110 of the drain 102 is configured to mate with the connector 156, as can be seen in Figure 18. In another preferred embodiment, the device 100 further comprises a sealant 158 for sealing the joint between the connector 156 and the adaptor 110, such as for example, an adhesive strip as shown in Figure 18.

In another embodiment, the present invention comprises a method of unoccluding an occluded drain. Referring now to Figure 19 through Figure 21, there are shown various

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steps in a method of unoccluding an occluded drain according to the present invention, using the drainage device shown in Figure 18, where Figure 19 is a partial cutaway, lateral perspective view of a drainage device shown in Figure 18 connected to a suction device, and with the distal end of the device within a drainage area; Figure 20 is a partial cutaway, 5 lateral perspective view of a drainage device shown in Figure 18 connected to a suction device, showing material occluding the central lumen of the drain; and Figure 21 is a partial cutaway, lateral perspective view of a drainage device shown in Figure 18 showing the occluding material being removed from the drain with the occlusion removing structure. As can be seen, the method comprises, first, providing a drainage device 100 according to 10 the present invention, such as the device shown in Figure 18. Then, the distal end 106 of the drain 102 is placed within an area to be drained 160 and allowed to drain drainage for the area, as shown in Figure 19. Next, after the central lumen 108 of the drain 102 is occluded with occluding material 134, as shown in Figure 20, the occlusion removing structure 150 is removed from the drain 102 by, first, disconnecting the connector 156 15 from the adaptor 110, and then applying proximal traction to the proximal end 152 of the occlusion removing structure 150, as shown in Figure 21, thereby removing the occluding material 134 within the occlusion removing structure 150 and unoccluding the drain 102. As proximal traction is applied to the occlusion removing structure 150, the mesh at the distal end 154 elongates, thereby constricting the tubular mesh around any occluding 20 material 134 within the central lumen 108 of the drain 102 and assisting in removing the occluding material 134. In one embodiment, the method comprises attaching the device 100 to a suction device 112 after placing the distal end 112 of the drain 102. In another embodiment, the method comprises reattaching the device 100 to the suction device 112 after removing the occlusion removing structure 150.

25 Referring now to Figure 22 through Figure 24, there are shown, respectively, a partial, cutaway, lateral perspective view of another embodiment of a drainage device according to the present invention comprising a drain with an occlusion removing structure (Figure 22); another partial, cutaway, lateral perspective view of the embodiment of the device shown in Figure 22 showing an occlusion being removed from the device according

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to the method of the present invention (Figure 23); and another partial, cutaway, lateral perspective view of the embodiment of the device shown in Figure 22 showing an occlusion being removed from the device according to the method of the present invention (Figure 24). As can be seen, in another embodiment of the present invention, the drainage device 5 100 comprises a drain 102 and an occlusion removing structure 162 comprising a proximal end 164, a distal end 166, and an intermediate segment 168 between the proximal end 164 and the distal end 166. The distal end 166 comprises an inflatable balloon 170. The proximal end 164 is an injection hub configured to mate with a source of inflation material, not shown, for example, an inflation fluid, such as saline, or an inflation gas. The 10 intermediate segment 168 comprises an inflation lumen extending from the proximal end 164 to the inflatable balloon 170 at the distal end 166. In a preferred embodiment, the proximal end 104 of the drain 102 further comprises a collapsible sleeve 172, as shown in Figure 22 through Figure 24. In another preferred embodiment, the drain 102 can also comprise a cap 128, not shown, on the proximal end 104 as disclosed in connection with 15 other embodiments of the device 100.

In another embodiment, the present invention comprises a method of unoccluding an occluded drain. Referring now to Figure 22 through Figure 24, the method comprises, first, providing a drainage device 100 according to the present invention, such as the device shown in Figure 22 through Figure 24. Next, the distal end 106 of the drain 102 is placed 20 within an area to be drained and allowed to drain drainage for the area with the inflatable balloon 170 initially in the uninflated state as shown in Figure 22. Then, after the central lumen 108 of the drain 102 is occluded with occluding material 134, as shown in Figure 22, the inflatable balloon 170 is inflated by injecting inflation material into the proximal end 164 of the occlusion removing structure 162 and through the intermediate segment 168 to the inflatable balloon 170. Next, the occlusion removing structure 162 is removed from 25 the drain 102 by proximally translating the occlusion removing structure 162, thereby removing the occluding material 134. The occluding material 134 is either removed from the proximal end 104 of the drain 102 or through the suction device 112, as shown in Figure 24.

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In one embodiment, the method further comprises replacing the occlusion removing structure 162 after the occlusion is removed. In another embodiment, the method comprises attaching the device 100 to a suction device 124 after placing the distal end 106 of the drain 102. In another embodiment, the method comprises reattaching the device 100 to the suction device 112 after removing the occlusion removing structure 162. In a preferred embodiment, the drain 102 comprises a collapsible sleeve 172, and the collapsible sleeve 172 is extended proximally as the occlusion removing structure 162 is removed from the drain 102 to maintain sterility of the occlusion removing structure 162, the collapsible sleeve 172 is collapsed as the occlusion removing structure 162 is reinserted into the drain 102. As will be understood by those with skill in the art with reference to this disclosure, when drain the 102 comprises a cap 128, removing the occlusion removing structure 162 comprises opening the cap 128 to permit the occlusion removing structure 162 to be removed from the drain 102.

In another embodiment of the present invention, there is provided a drainage device 100 comprising a plurality of different occlusion removing structures as disclosed in the various embodiments of the device 100. In such an embodiment, the drain 102 is unoccluded using either one of the occlusion removing structures or using a plurality of the occlusion removing structures. The drainage device can comprise any of the occlusion removing structures disclosed in this disclosure in combination, as will be understood by those with skill in the art with reference to this disclosure. For example, the device 100 can comprise an occlusion removing structure 116 comprising one or more than one tubular structure with an occlusion removing structure 162 comprising an inflatable balloon. In a preferred embodiment, the device 100 comprises an occlusion removing structure 116 comprising a plurality of co-axial tubular structures with an occlusion removing structure 162 comprising an inflatable balloon between each of the plurality of co-axial tubular structures. This embodiment is particularly suitable for use as in-dwelling feeding and infusion tubes, where the inflatable balloon 170 is kept inflated between periods of infusion. In another preferred embodiment, the device 100 comprises a tubular mesh occlusion removing structure 136, 142 with an occlusion removing structure 162

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comprising an inflatable balloon.

Although the present invention has been discussed in considerable detail with reference to certain preferred embodiments, other embodiments are possible. Therefore, the scope of the appended claims should not be limited to the description of preferred 5 embodiments contained in this disclosure.

WHAT IS CLAIMED IS:

1. A drainage device comprising means for drainage and means for removing an occlusion.

2. A method of unoccluding a means for drainage comprising:

5 a) providing the drainage device of claim 1;

b) placing the drainage device into an area to be drained;

c) allowing occluding material to occlude the means for drainage; and

d) removing the means for removing an occlusion from the means for drainage,

thereby unoccluding the means for drainage.

10 3. A drainage device comprising:

a) a drain comprising a proximal end, a distal end and a central lumen; and

b) an occlusion removing structure within the central lumen comprising a proximal end and a distal end;

15 where the proximal end of the drain comprises an adaptor configured to mate with a suction device;

where the distal end of the drain comprises one or more than one aperture;

where the occlusion removing structure comprises one or more than one tubular structure comprising a wall; and

20 where the distal end of the occlusion removing structure comprises one or more than one aperture.

4. The drainage device of claim 3, further comprising a suction device mated with the adapter.

5. The drainage device of claim 3, where the occlusion removing structure comprises a plurality of co-axial tubular structures.

25 6. The drainage device of claim 3, where the number of the one or more than one aperture on the distal end of the drain is equal to the number of the one or more than one aperture on the distal end of the occlusion removing structure.

7. The drainage device of claim 3, where the proximal end of the occlusion removing structure comprises an appendage.

8. The drainage device of claim 7, where the appendage comprises an identification tag.

9. The drainage device of claim 3, where the proximal end of the drain comprises a cap.

5 10. The drainage device of claim 3, where the occlusion removing structure comprises an outer surface, the drain comprises an inner surface, and where the outer surface of the occlusion removing structure, or the inner surface of the drain, or both have a lubricious coating.

10 11. The drainage device of claim 3, where the drain further comprises one or more than one structure for securing the proximal end of the device.

12. The drainage device of claim 3, where the wall comprises a snare.

15 13. The drainage device of claim 3, where the occlusion removing structure is a first occlusion removing structure, and where the device further comprises a second occlusion removing structure comprising a proximal end, a distal end, an intermediate segment between the proximal end and the distal end, and an inflation balloon on the distal end.

14. A method of unoccluding a drainage device comprising:

- a) providing the drainage device of claim 3;
- b) placing the distal end of the drain into an area to be drained;
- c) allowing occluding material to occlude the drain; and
- d) removing the occlusion removing structure from the drain, thereby unoccluding the drain.

20 15. The method of claim 14, further comprising attaching the drainage device to a suction device after placing the distal end of the drain.

25 16. The method of claim 14, further comprising reattaching the drainage device to the suction device after removing the occluding material removing structure.

17. The method of claim 14, where the occlusion removing structure comprises an appendage, and where removing the occlusion removing structure comprises applying proximal traction to the appendage, thereby translating the occlusion removing structure

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proximally.

18. The method of claim 14, where the drain comprises a cap, and where removing the occlusion removing structure comprises opening the cap to permit the occlusion removing structure to be removed from the drain.

5 19. The method of claim 14, where the occlusion removing structure comprises a plurality of co-axial tubular structures, and where removing the occlusion removing structure preferably comprises removing only one of the plurality of co-axial tubular structures.

10 20. The method of claim 19, further comprising infusing a fluid between each of the plurality of co-axial tubular structures to facilitate separation of the co-axial structures from each other.

15 21. The method of claim 14, where the wall comprises a snare, and where removing the occlusion removing structure comprises applying proximal traction to the proximal end of the snare causes the distal end of the occlusion removing structure to contract in a purse-string type fashion, thereby substantially or completely sealing the distal end of the occlusion removing structure.

20 22. A drainage device comprising:
a) a drain comprising a proximal end, a distal end and a central lumen; and
b) an occlusion removing structure within the central lumen comprising a proximal end and a distal end;

where the proximal end of the drain comprises an adaptor configured to mate with a suction device;

where the distal end of the drain comprises one or more than one aperture; and where the occlusion removing structure comprises a tubular mesh.

25 23. The drainage device of claim 22, where the proximal end of the occlusion removing structure comprises a plurality of loops.

24. The drainage device of claim 22, further comprising a suction device mated with the adapter.

25. The drainage device of claim 22, where the proximal end of the occlusion

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removing structure comprises an appendage.

26. The drainage device of claim 22, where the proximal end of the drain comprises a cap.

5 27. The drainage device of claim 22, where the drain further comprises one or more than one structure for securing the proximal end of the device.

28. The drainage device of claim 22, where the occlusion removing structure comprises a connector on the proximal end.

10 29. The drainage device of claim 27, where the device further comprises a joint between the adaptor and the connector, and further comprising a sealant for sealing the joint between the connector and the adaptor.

15 30. The drainage device of claim 22, where the occlusion removing structure is a first occlusion removing structure, and where the device further comprises a second occlusion removing structure comprising a proximal end, a distal end, an intermediate segment between the proximal end and the distal end, and an inflation balloon on the distal end.

20 31. A method of unoccluding a drainage device comprising:
a) providing the drainage device of claim 22;
b) placing the distal end of the drain into an area to be drained;
c) allowing occluding material to occlude the drain; and
d) removing the occlusion removing structure from the drain, thereby unoccluding the drain.

32. The method of claim 31, further comprising attaching the drainage device to a suction device after placing the distal end of the drain.

25 33. The method of claim 31, further comprising reattaching the drainage device to the suction device after removing the occluding material removing structure.

34. The method of claim 31, where the occlusion removing structure comprises an appendage, and where removing the occlusion removing structure comprises applying proximal traction to the appendage, thereby translating the occlusion removing structure proximally.

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35. The method of claim 31, where the drain comprises a cap, and where removing the occlusion removing structure comprises opening the cap to permit the occlusion removing structure to be removed from the drain.

5 36. The method of claim 31, where the proximal end of the occlusion removing structure comprises loops, and where removing the occlusion removing structure from the drain comprises pulling the proximal end of the occlusion removing structure into a sheath.

. 37. The method of claim 31, further comprising replacing the occlusion removing structure in the drain after unoccluding the drain.

10 38. The method of claim 36, where replacing the occlusion removing structure in the drain after unoccluding the drain comprises advancing an introducer containing the replacement occlusion removing structure through the proximal end of the drain until the distal end of the replacement occlusion removing structure is placed at or near the distal end of the drain, and then removing the introducer leaving the replacement occlusion removing structure within the drain.

15 39. A drainage device comprising:

a) a drain comprising a proximal end, a distal end and a central lumen; and
b) an occlusion removing structure within the central lumen comprising a proximal end, a distal end and an intermediate segment between the proximal end and the distal end;
where the proximal end of the drain comprises an adaptor configured to mate with a
20 suction device;

where the distal end of the drain comprises one or more than one aperture; and
where the occlusion removing structure comprises an inflation balloon on the distal end.

25 40. The drainage device of claim 39, where the drain further comprises a suction device mated with the adapter.

41. The drainage device of claim 39, where the proximal end of the drain comprises a cap.

42. The drainage device of claim 39, where the drain further comprises one or more than one structure for securing the proximal end of the device.

43. The drainage device of claim 39, where the drain further comprises a collapsible sleeve.

44. A method of unoccluding a drainage device comprising:

- a) providing the drainage device of claim 39;
- b) placing the distal end of the drain into an area to be drained;
- c) allowing occluding material to occlude the drain;
- d) inflating the inflatable balloon; and
- e) removing the occlusion removing structure from the drain, thereby unoccluding the drain.

10 45. The method of claim 44, further comprising attaching the drainage device to a suction device after placing the distal end of the drain.

46. The method of claim 44, further comprising reattaching the drainage device to the suction device after removing the occluding material removing structure.

15 47. The method of claim 44, where the drain comprises a cap, and where removing the occlusion removing structure comprises opening the cap to permit the occlusion removing structure to be removed from the drain.

48. The method of claim 44, further comprising replacing the occlusion removing structure in the drain after unoccluding the drain.

20 49. The method of claim 44, where the drain further comprises a collapsible sleeve, and where the collapsible sleeve is extended proximally as the occlusion removing structure is removed from the drain.

14853-2PCT

ABSTRACT

A drainage device (100) comprising means for drainage (102) and means for removing an occlusion (116, 136, 150). A method of unoccluding a means for drainage comprising a) providing the drainage device (100) according to the present invention; b) placing the drainage device into an area to be drained; c) allowing occluding material (134) to occlude the means for drainage (102); and d) removing the means for removing an occlusion (116, 136, 150) from the means for drainage (102), thereby unoccluding the means for drainage (102).

A drainage device (100) comprising means for drainage (102) and means for removing an occlusion (116, 136, 150). A method of unoccluding a means for drainage comprising a) providing the drainage device (100) according to the present invention; b) placing the drainage device into an area to be drained; c) allowing occluding material (134) to occlude the means for drainage (102); and d) removing the means for removing an occlusion (116, 136, 150) from the means for drainage (102), thereby unoccluding the means for drainage (102).

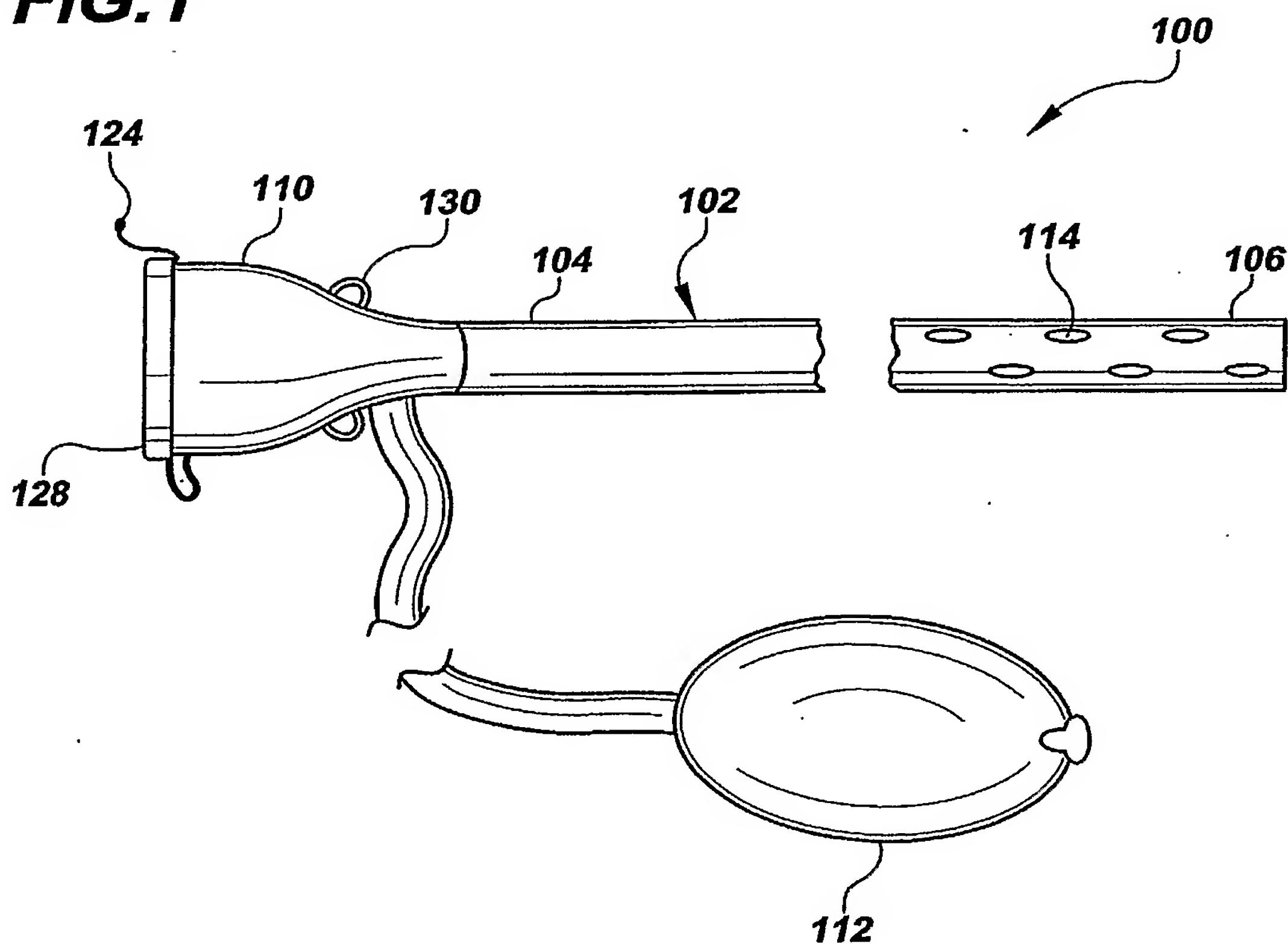
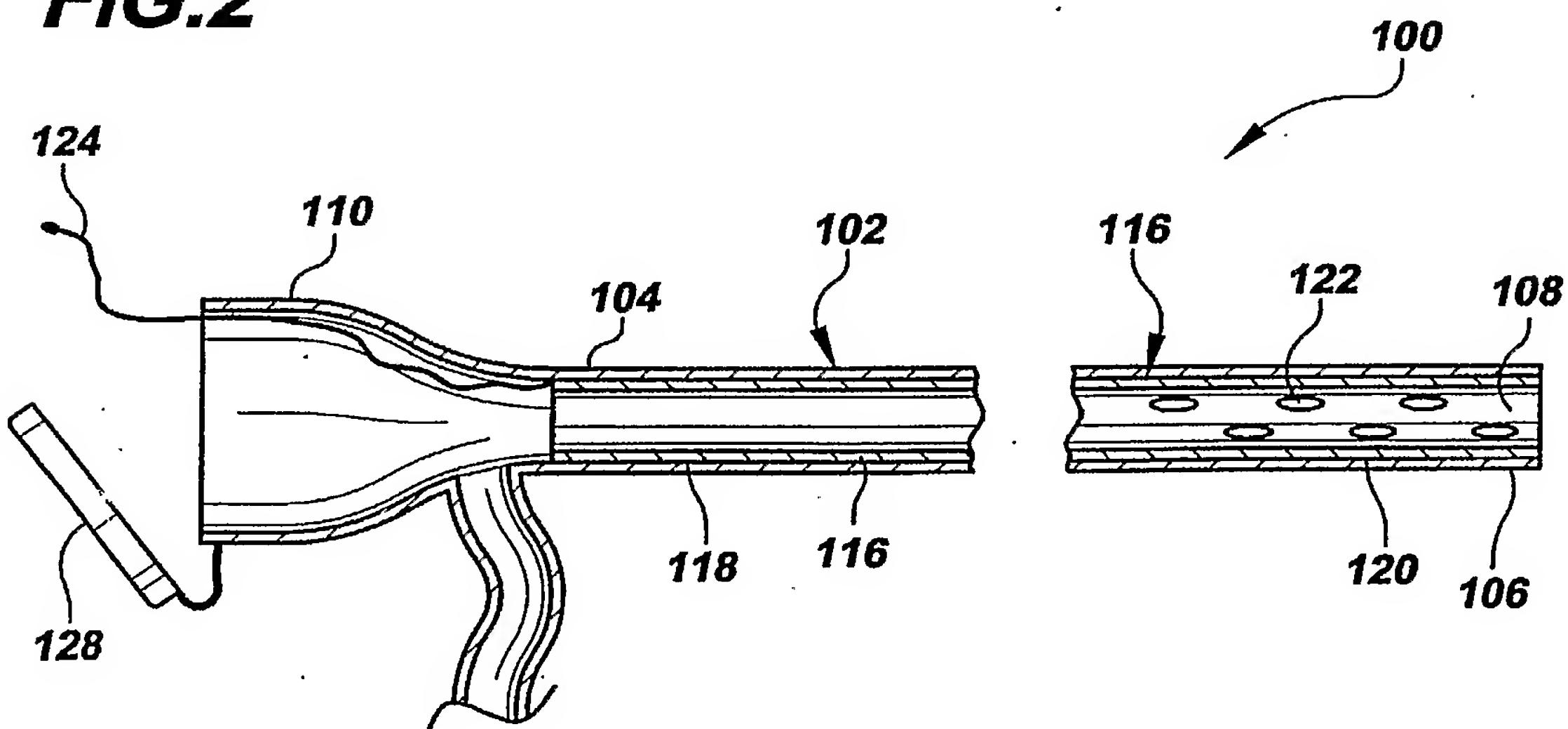
FIG. 1**FIG. 2**

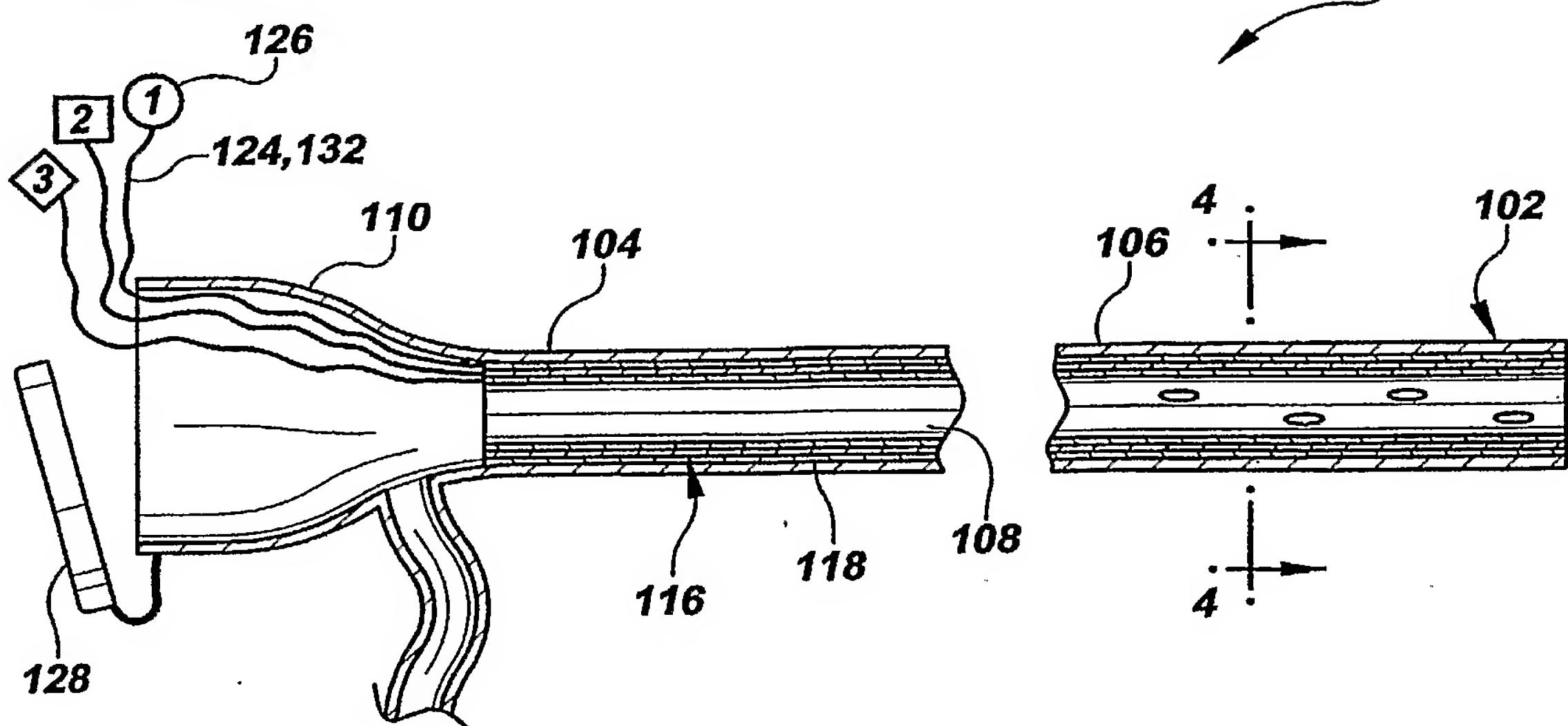
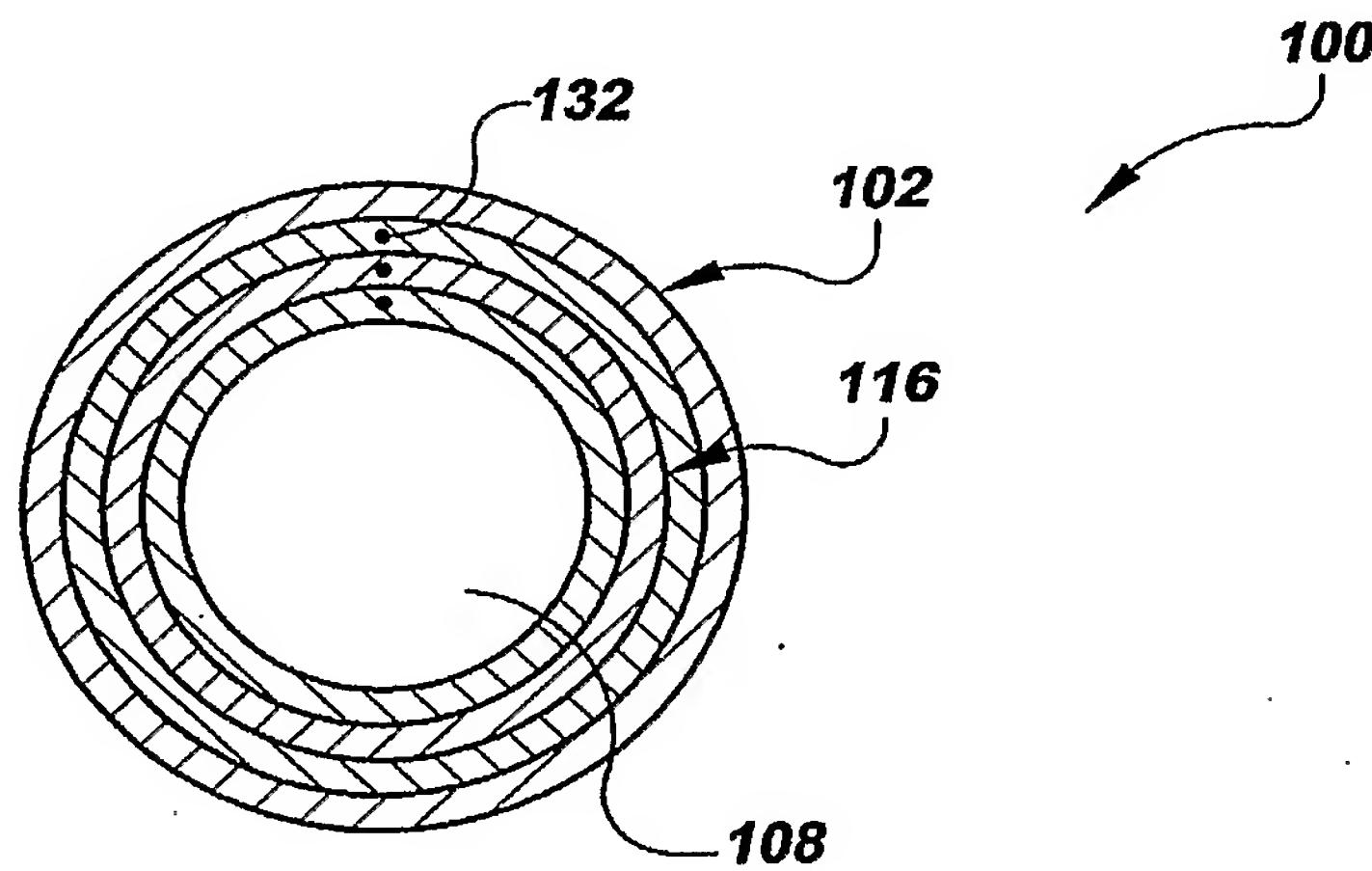
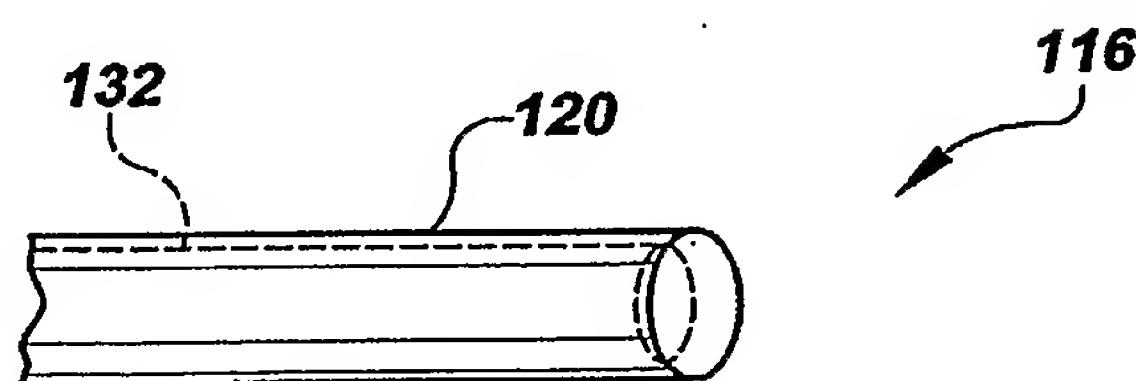
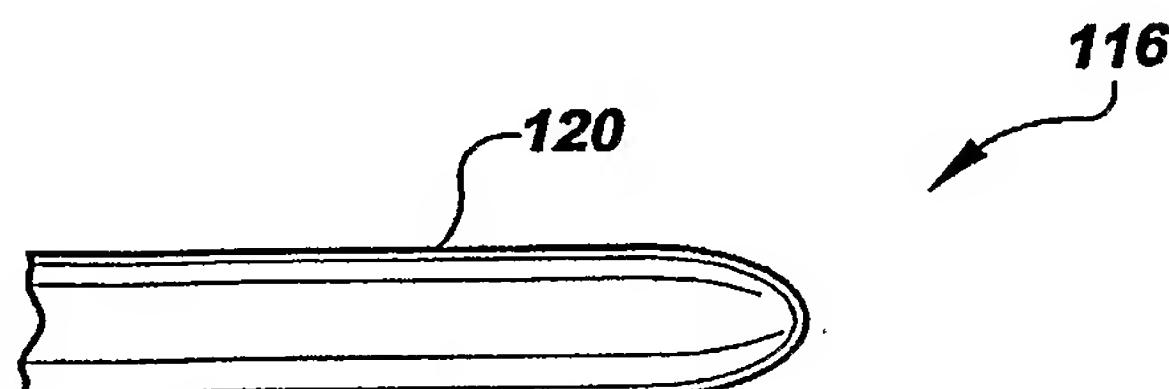
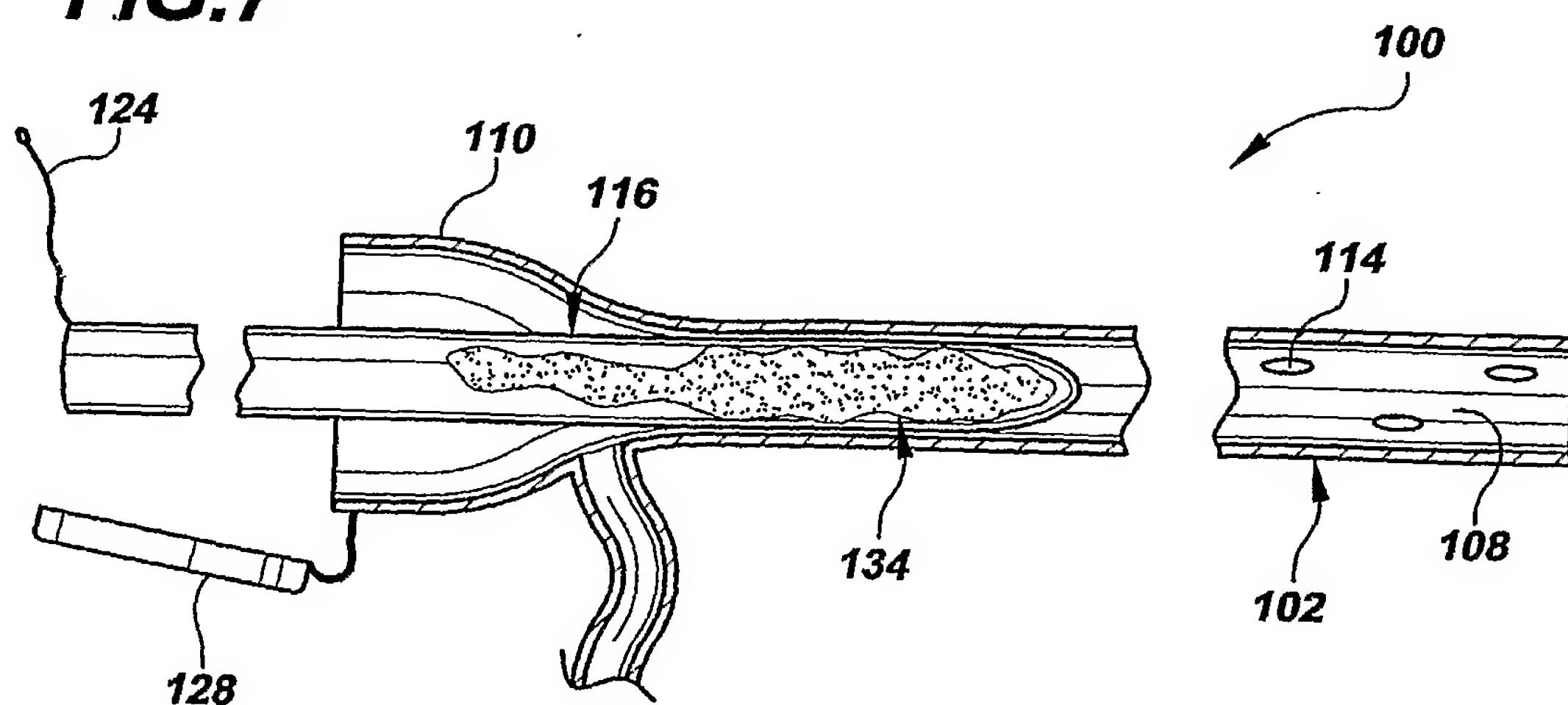
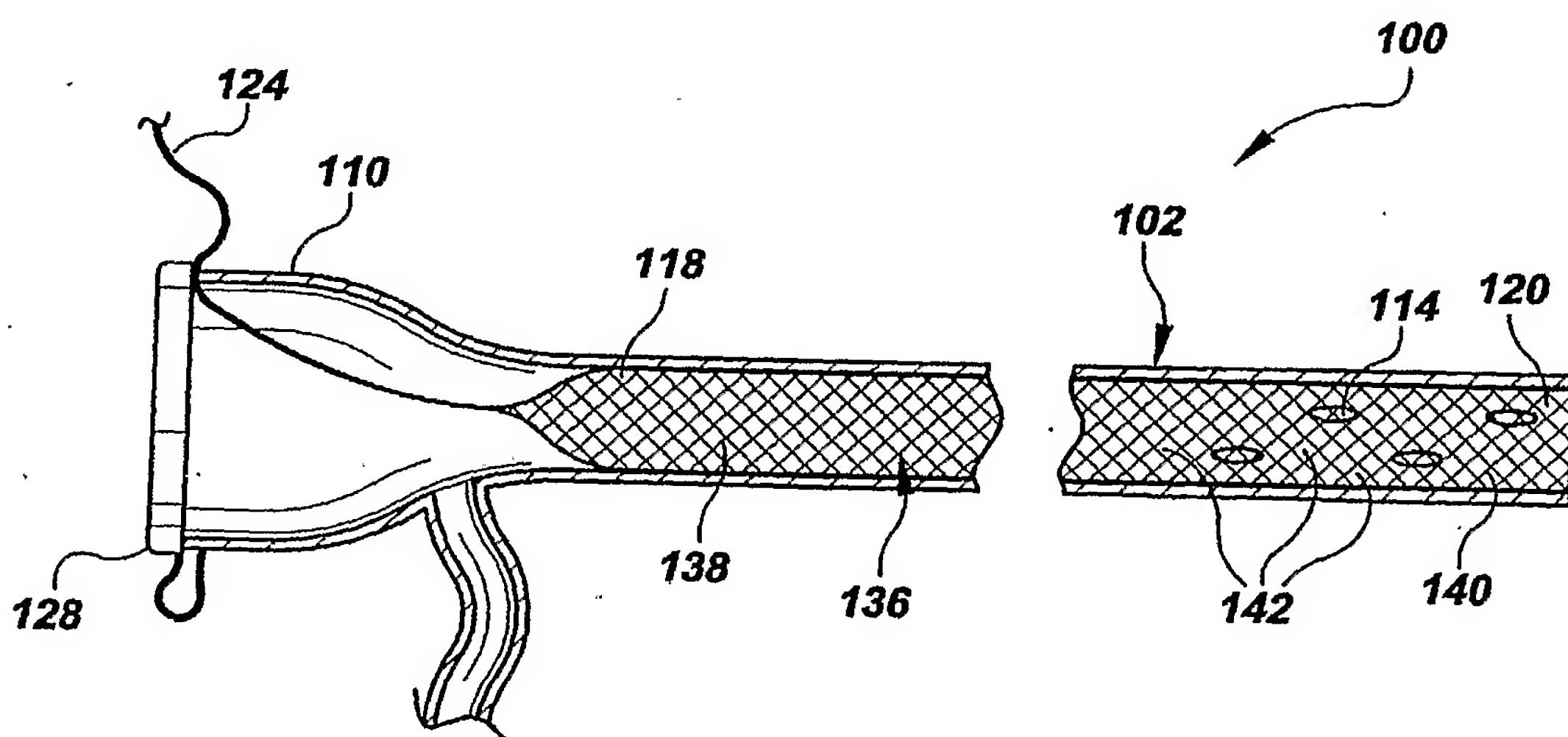
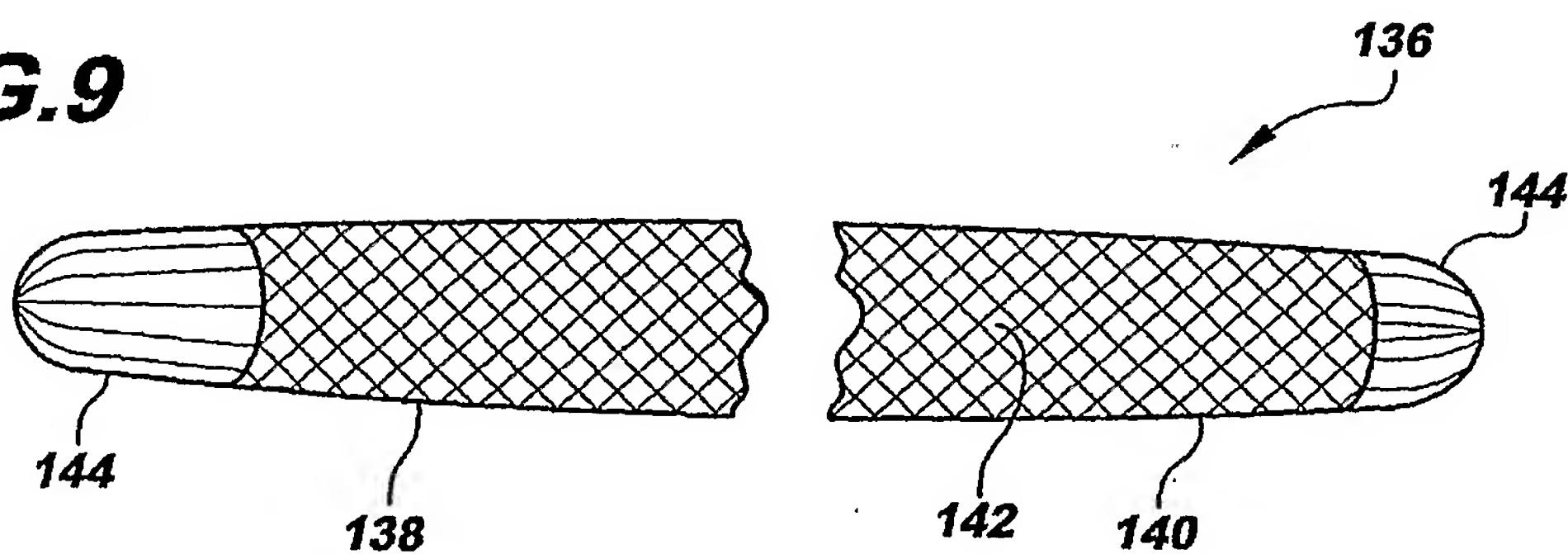
FIG.3**FIG.4****FIG.5****FIG.6**

FIG.7

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**FIG.8****FIG.9**

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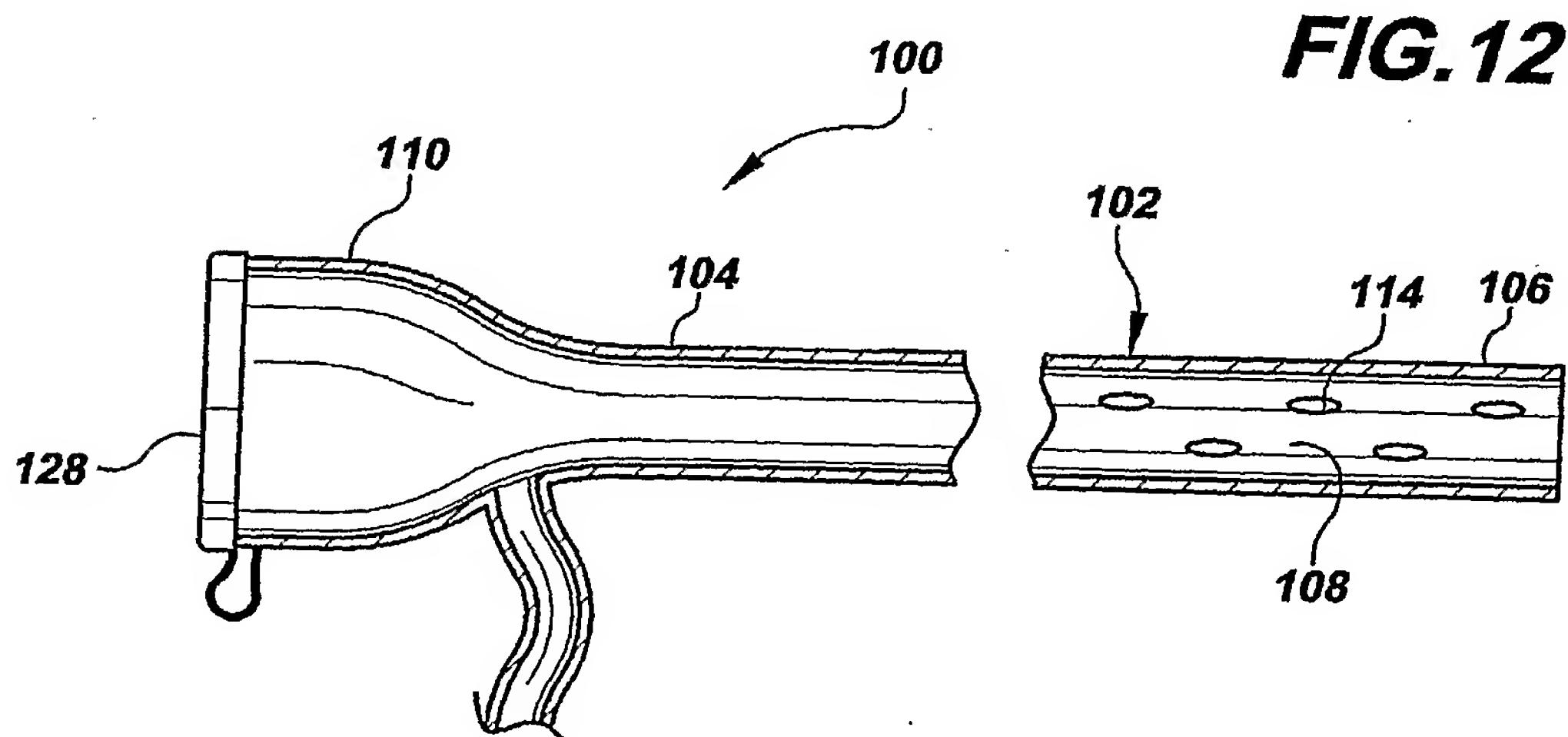
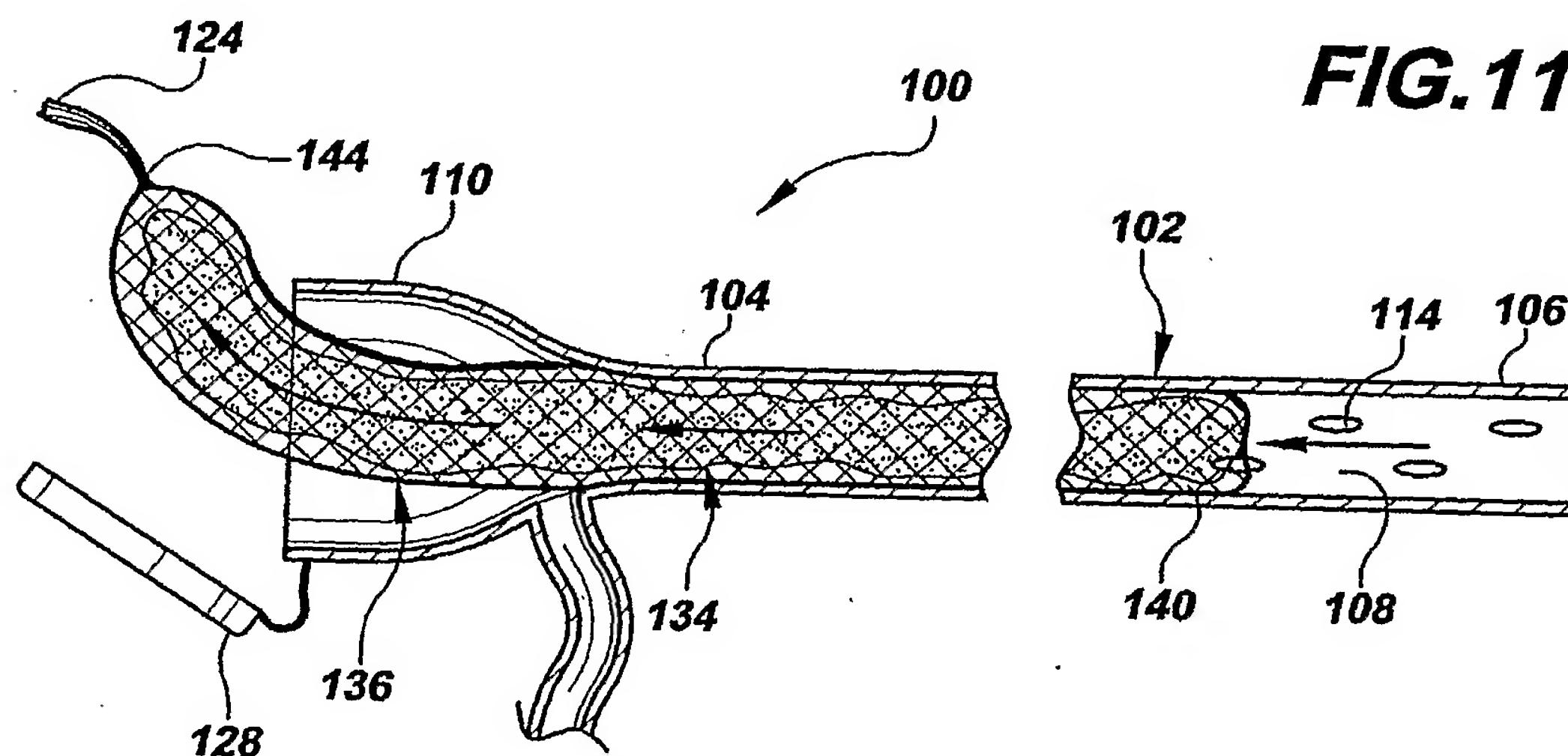
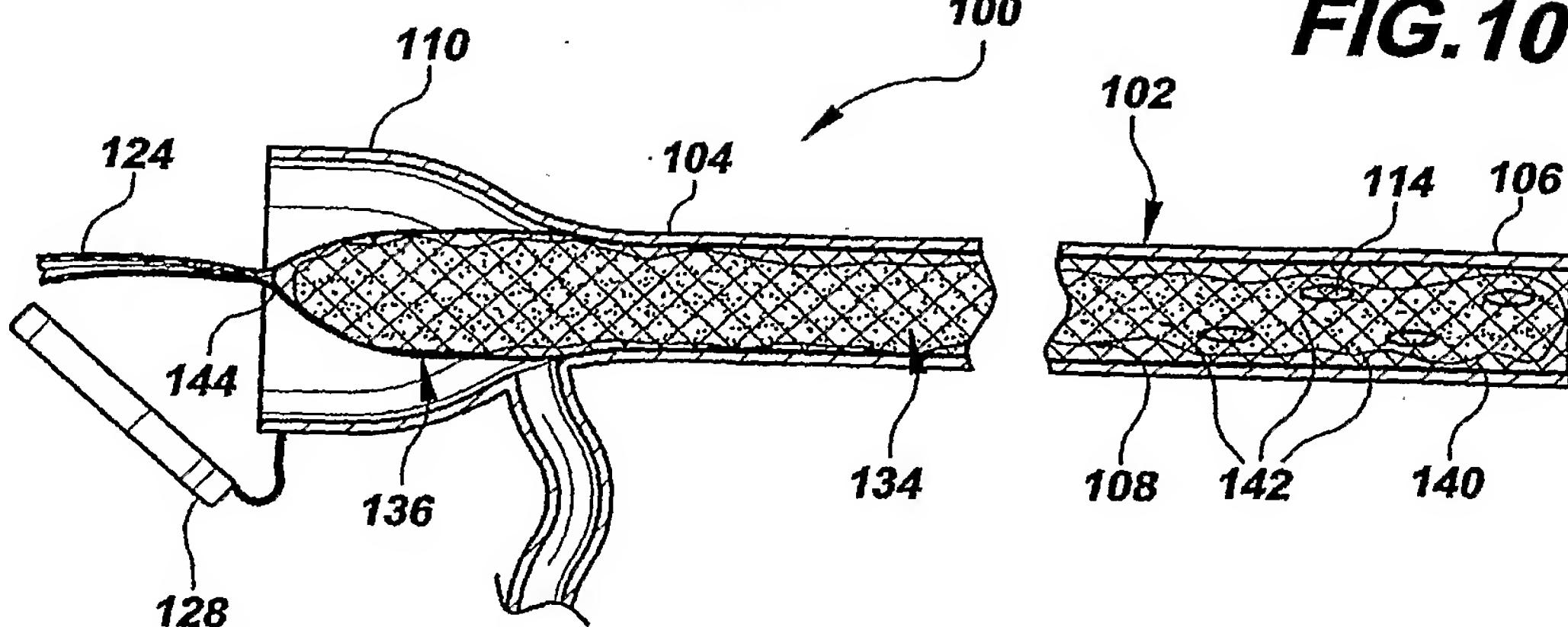


FIG. 13

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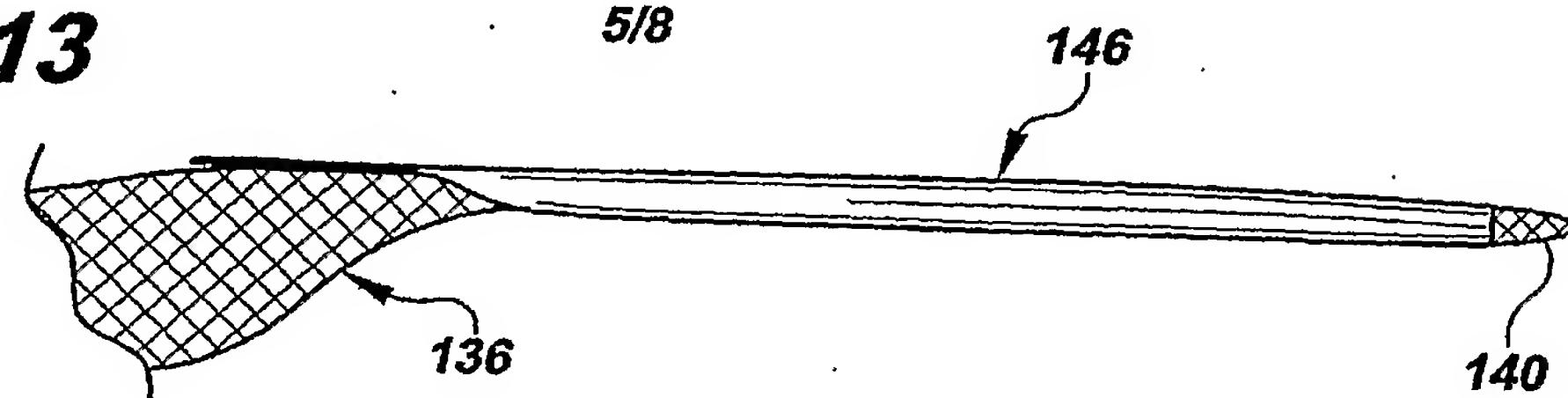


FIG. 14

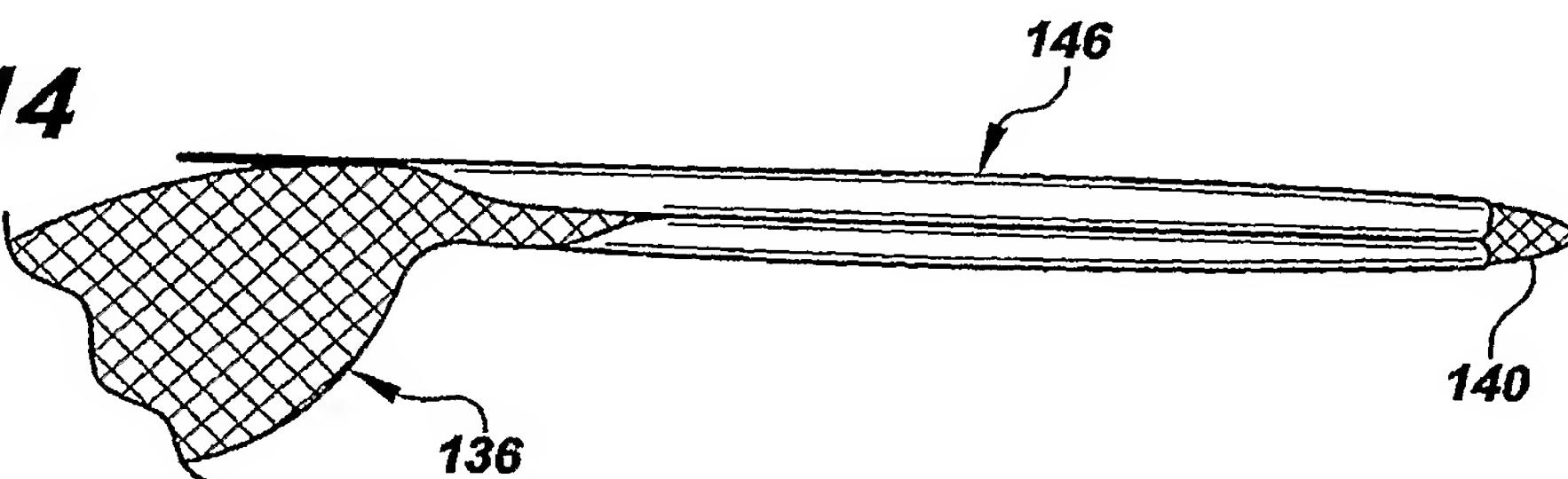


FIG. 15

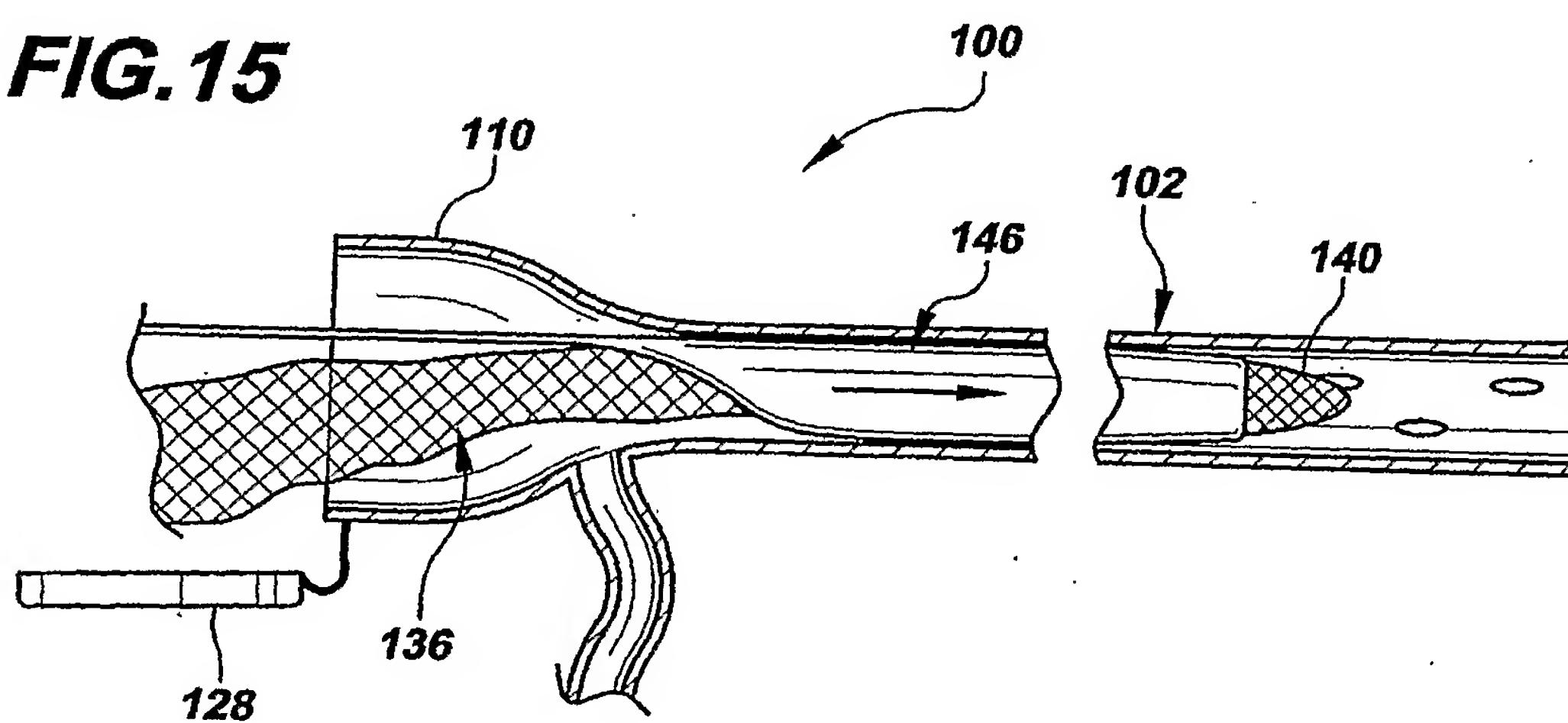


FIG. 16

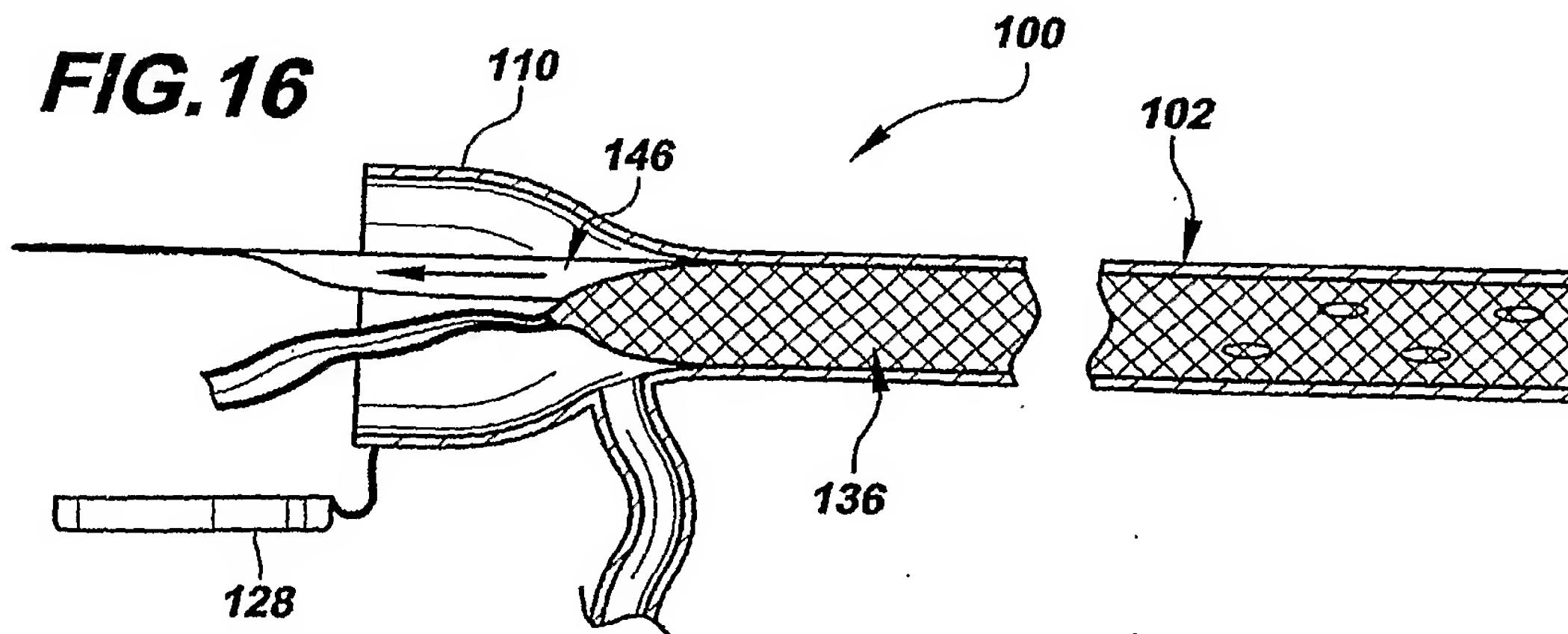


FIG.17

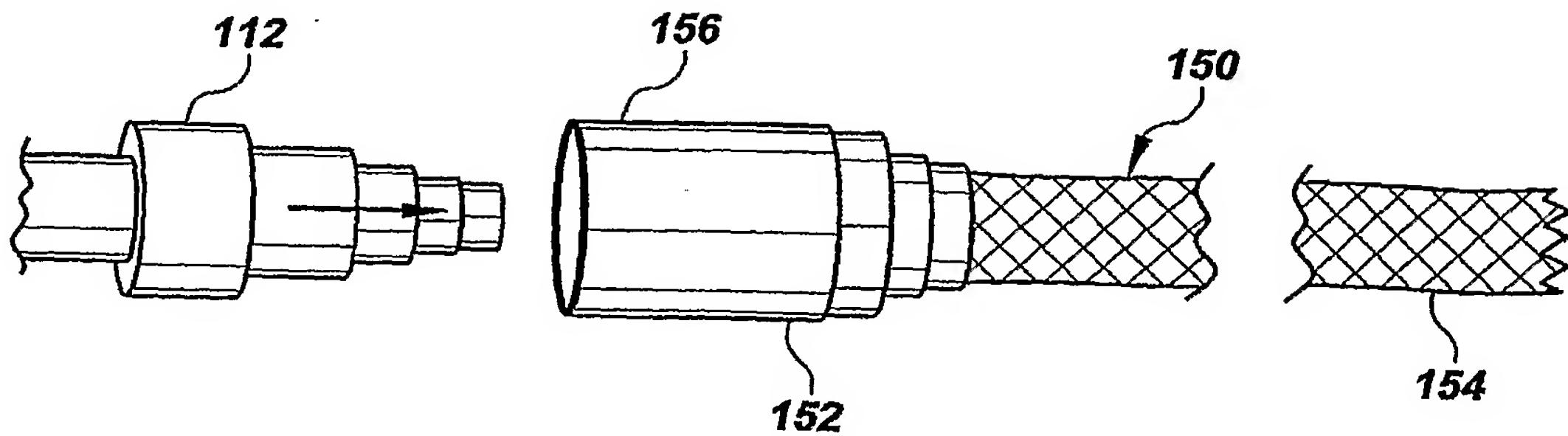


FIG. 18

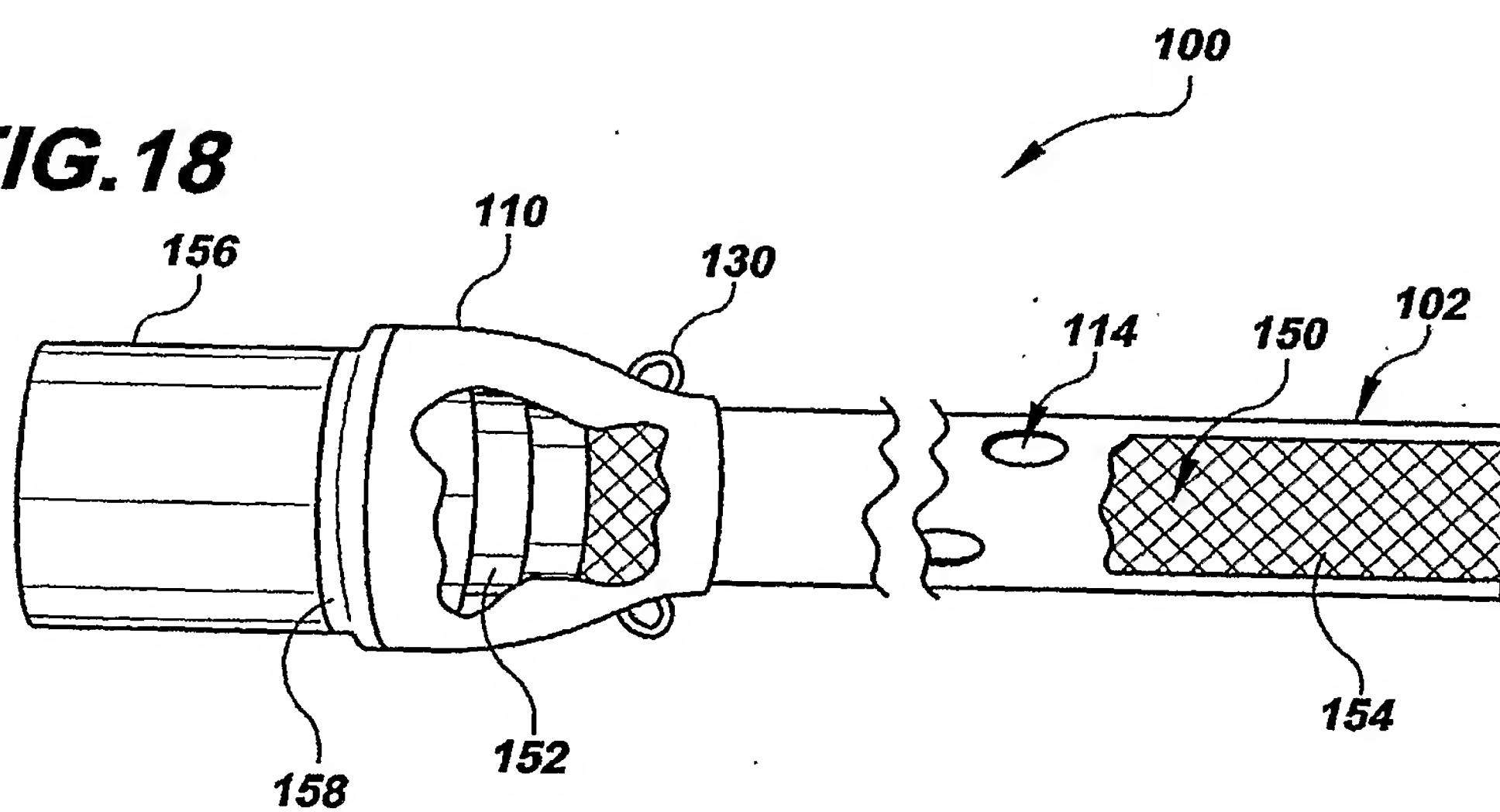


FIG.19

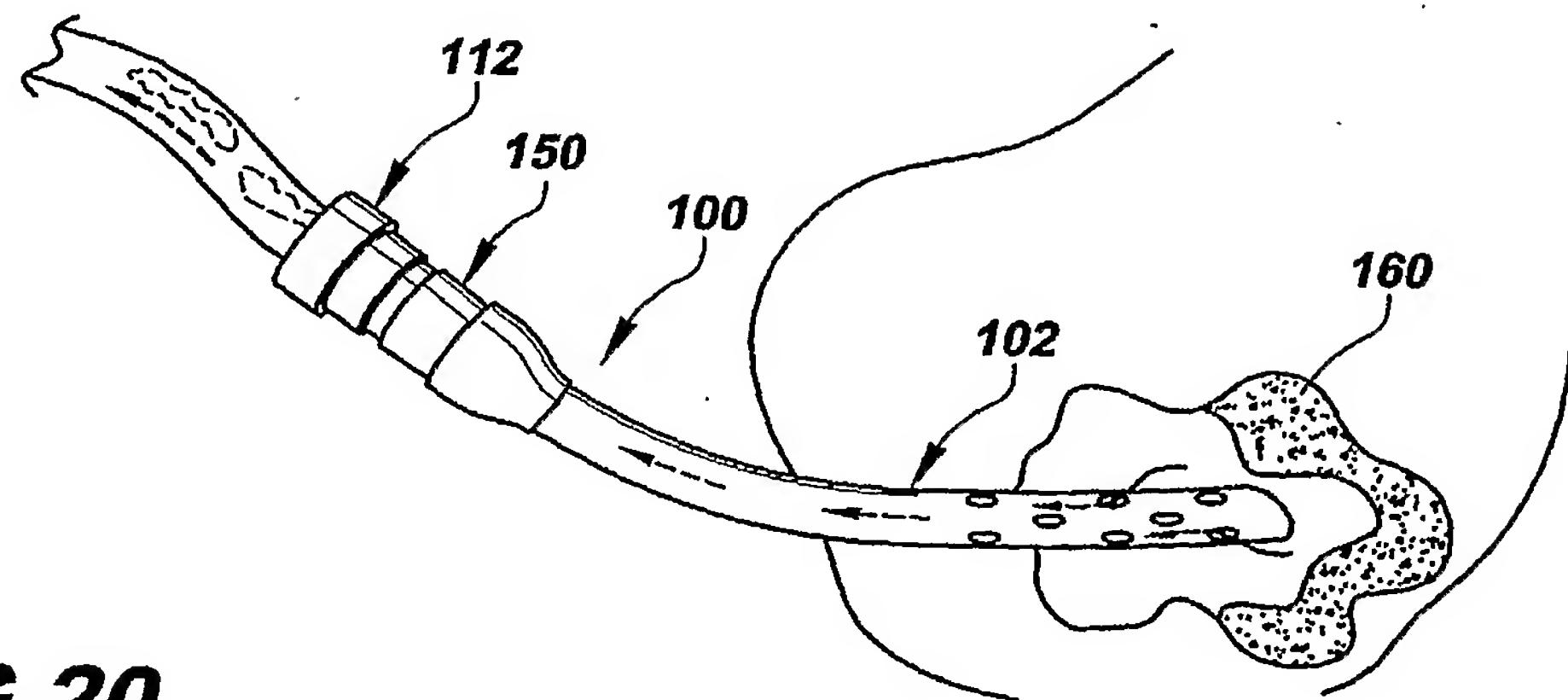


FIG.20

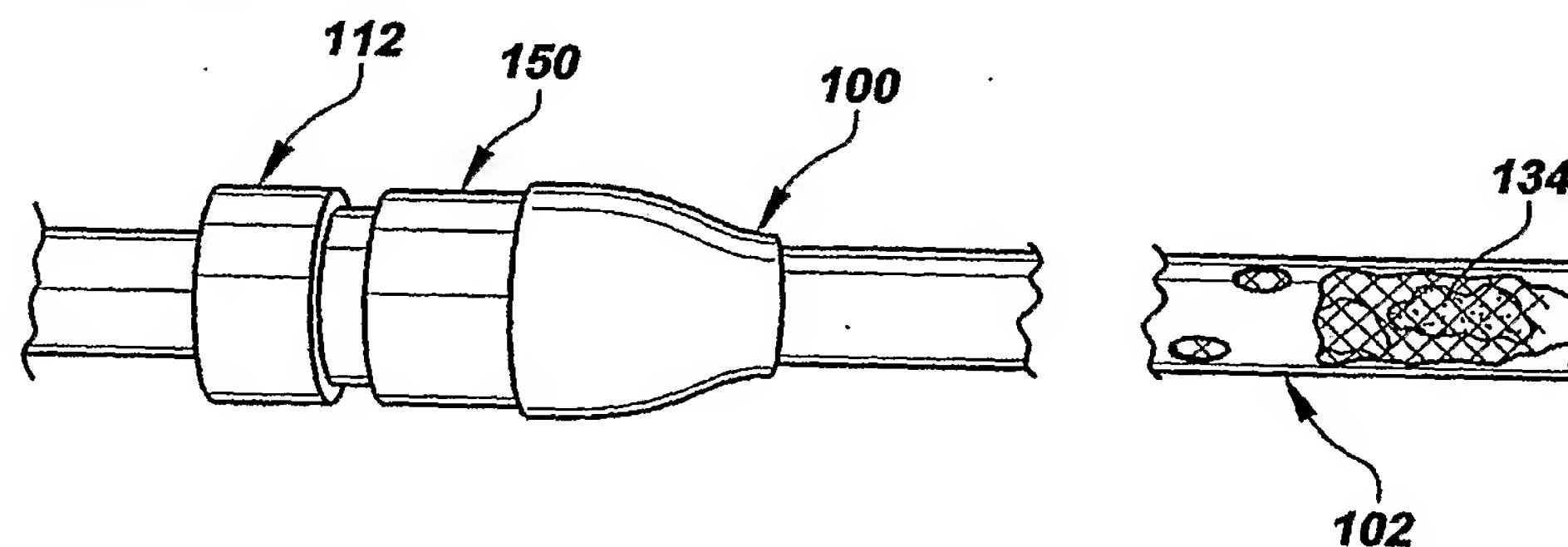


FIG.21

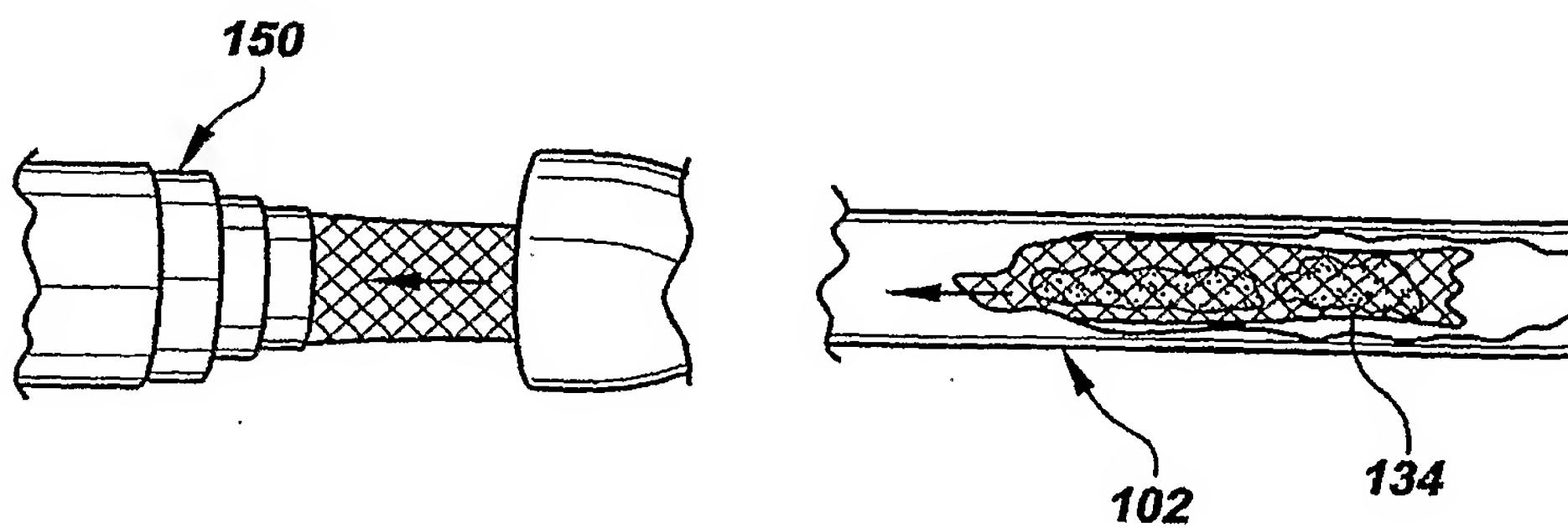
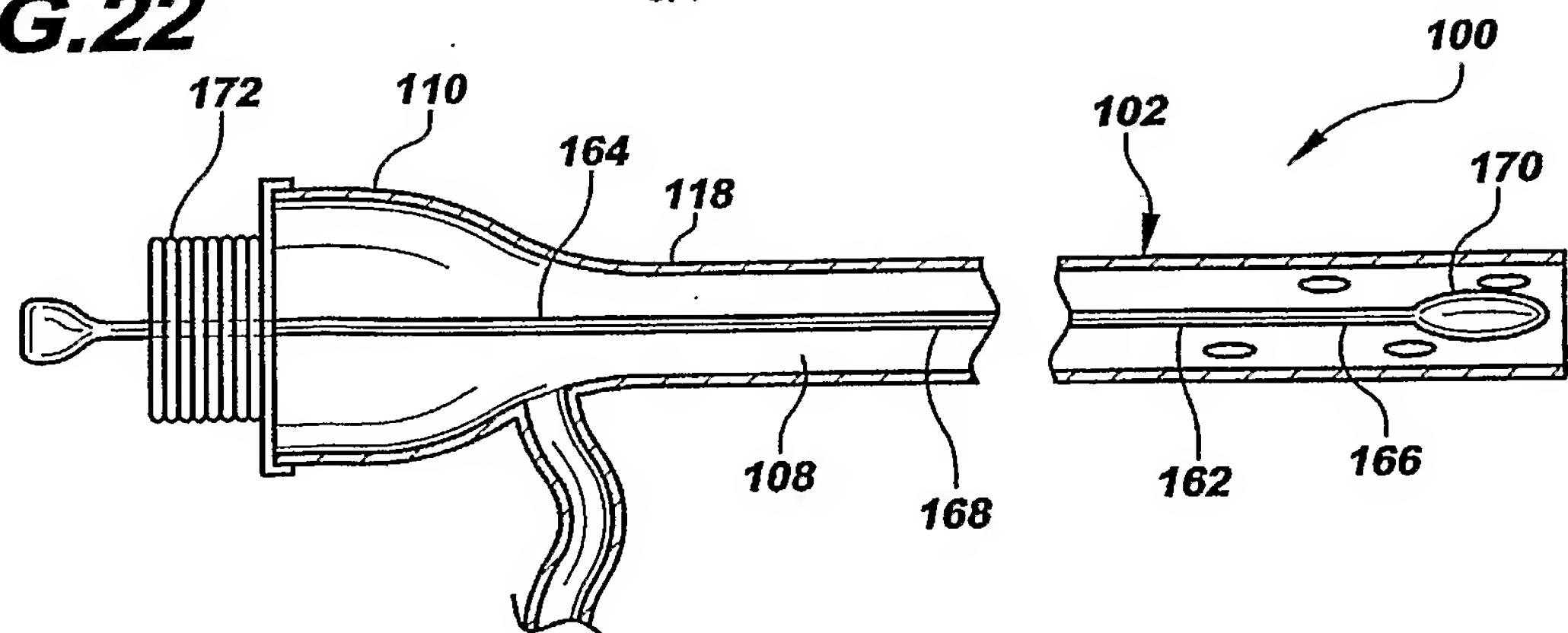
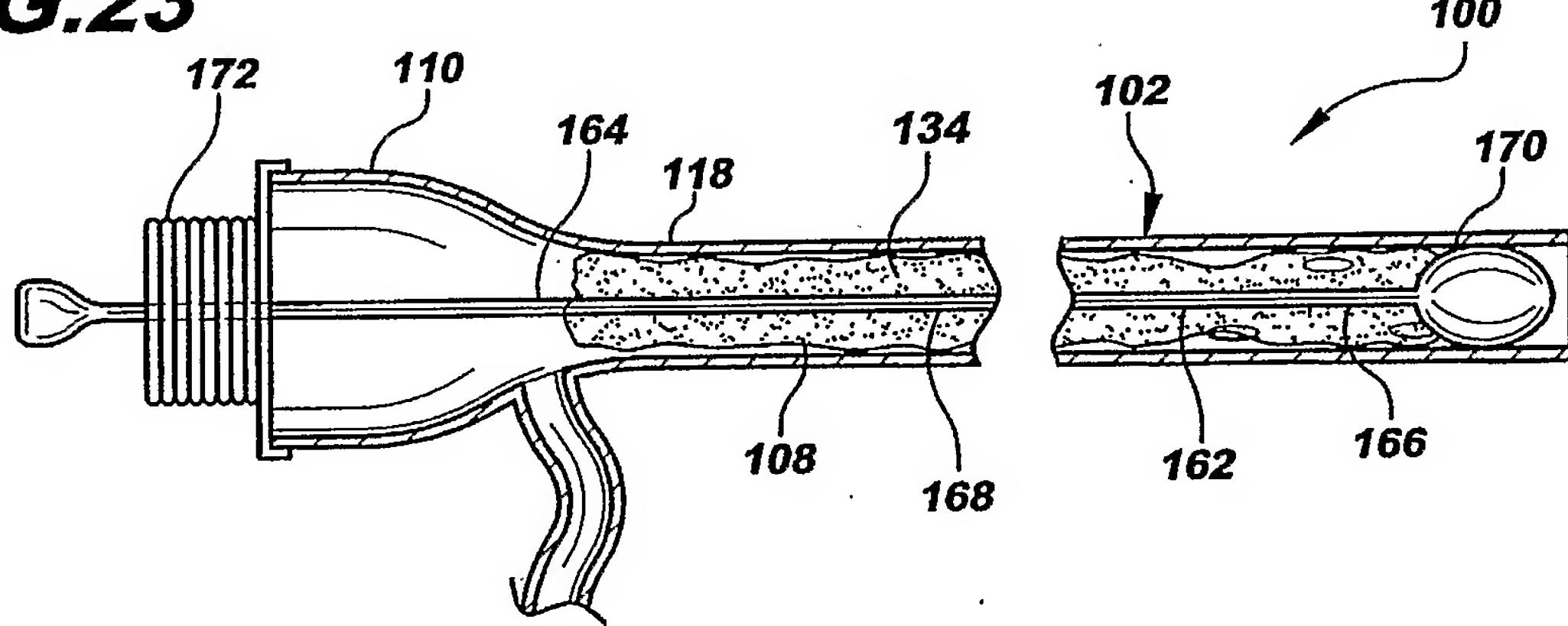
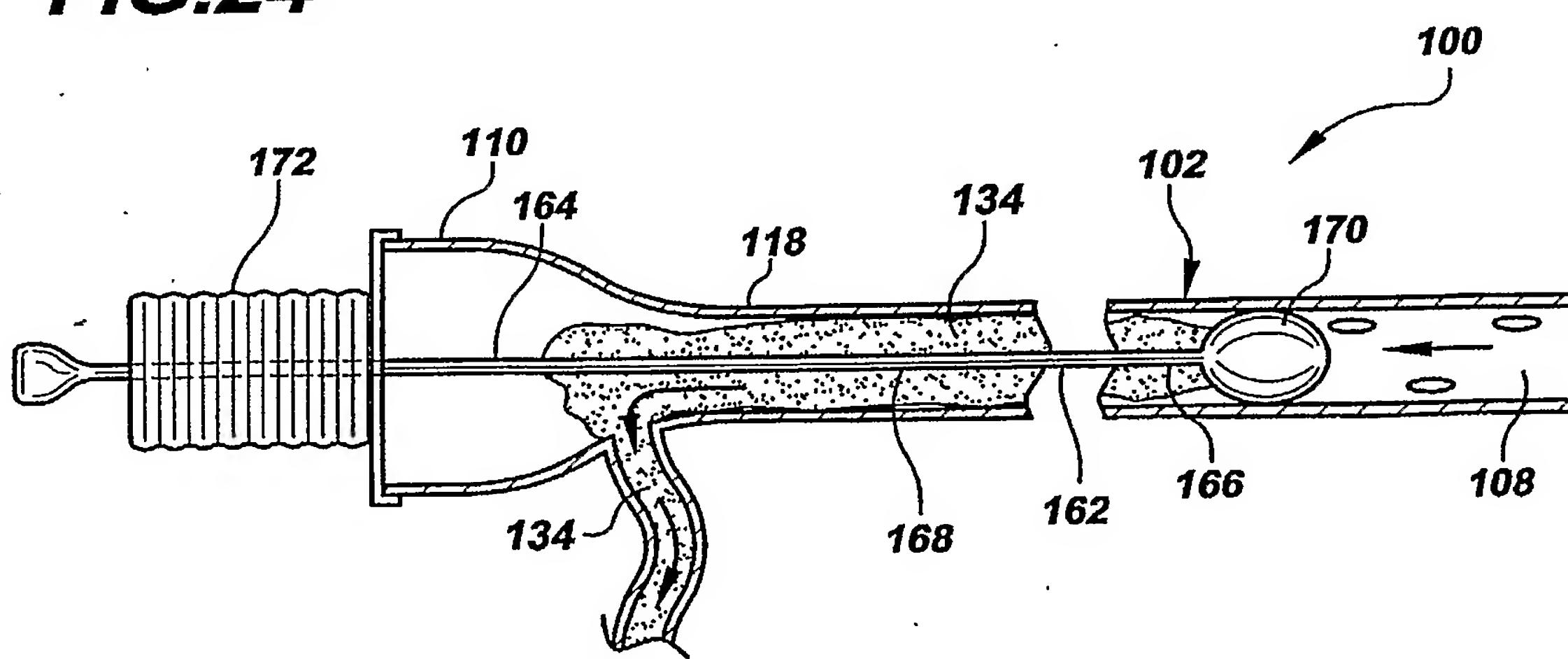


FIG.22

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**FIG.23****FIG.24**

PATENT COOPERATION TREATY

From the RECEIVING OFFICE

To:

DAVID A. FARAH
SHELDON & MAK PC
225 SOUTH LAKE AVENUE
SUITE 900
PASADENA, CALIFORNIA 91101

PCT

**NOTIFICATION CONCERNING PAYMENT
OF PRESCRIBED FEES**

(PCT Rules 14, 15 and 16 and Administrative Instructions, Sections 102bis(c), 304, 323(b), 707(b) and 803)

		Date of mailing (day/month/year)	04 Mar 2005
Applicant's or agent's file reference 14853-2PCT		PAYMENT DUE see item 3 for time limits	
International application No. PCT/US2005/000508	International filing date/Date of receipt (day/month/year)	07 Jan 2005	Priority date (day/month/year) 09 Jan 2004
Applicant THE CATHETER EXCHANGE, INC.			

1. The applicant is hereby notified that this receiving Office has received:

the payment of all the prescribed fees, and an overpayment, which will be refunded in due course.
 no or insufficient payment of the prescribed fees and the applicant is hereby invited to pay the balance due, as summarized under item 2, within the time limit(s) indicated under item 3.

2. Fees and payment calculation:

2,525.00	- 2,525.00	= 0.00
Total fees payable	Amount paid	Balance

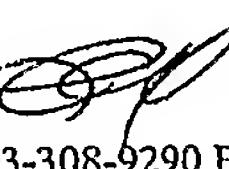
The details of the calculation are given in the Annex.

3. Time limit(s) for payment and amount(s) payable (Rules 14.1, 15.4 and 16.1(f)):

within ONE MONTH from the date of receipt of the international application (for the transmittal fee (if any), the search fee and the international filing fee). The amount payable for each fee is the amount applicable on the date of receipt of the international application.
 within 16 MONTHS from the priority date (only for the fee for priority document). The applicant's attention is drawn to the fact that the request made by the applicant under Rule 17.1(b) will be considered not to have been made unless the fee is paid within that time limit.

4. Additional observations (if necessary):

The search copy will not be transmitted to the International Searching Authority until the search fee is paid (therefore the start of the international search will be delayed) (Rule 23.1(a) and (b)).

Name and mailing address of the receiving Office Mail Stop PCT, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 703-305-3230	Authorized officer Rita Dozier  Telephone No. 703-308-9290 EX 119
---	--

ANNEX TO FORM PCT/RO/102
CALCULATION OF THE PRESCRIBED FEES

International application No.

PCT/US2005/000508

[T] Transmittal Fee

Prescribed amount:	300.00	[T]
Amount paid:	300.00	
Balance:	0.00	

correct amount
 overpayment
 balance due

[S] Search Fee

Prescribed amount:	1,000.00	[S]
Amount paid:	1,000.00	
Balance:	0.00	

correct amount
 overpayment
 balance due

[I] International Filing Fee

Fixed amount for first 30 sheets: 1,053.00 [i1]

11 x 12.00 = 132.00 [i2]

Number of sheets Fee per sheet
 in excess of 30

Additional component: 400 x 0.00 = 0.00 [i3]
 Fee per sheet

Reduction where the international application is filed
*(See PCT Applicant's Guide, Volume I, General Part,
 for details on the availability of this reduction):*

using the PCT-EASY software: - 0.00 [r]

or

in electronic form where the text of the
 description, claims and abstract is not in
 character coded format: - 0.00 [r]

or

in electronic form where the text of the
 description, claims and abstract is in character
 coded format: - 0.00 [r]

Sub-total: = 1,185.00 [i1+i2+i3-r]

Prescribed total amount (*The amount to be entered at I is the sub-total entered at (i1+i2+i3-r), except where the applicant is (or all applicants are) entitled to a reduction of 75%, in which case the amount to be entered at I is 25% of the sub-total (i1+i2+i3-r); certain applicants from certain States are entitled to a reduction of 75% of the international filing fee; see Notes to the Fee Calculation Sheet as annexed to the Request Form, PCT/RO/101, for details*): = 1,185.00 [I]

Amount paid: = 1,185.00

Balance: = 0.00

correct amount
 overpayment
 balance due

[P] Fee for Priority Document

Prescribed amount: = 40.00 [P]

Amount paid: = 40.00

Balance: = 0.00

correct amount
 overpayment
 balance due

PATENT COOPERATION TREATY

From the RECEIVING OFFICE

To:
 DAVID A. FARAH
 SHELDON & MAK PC
 225 SOUTH LAKE AVENUE
 SUITE 900
 PASADENA, CALIFORNIA 91101

PCT

**NOTIFICATION OF THE INTERNATIONAL
APPLICATION NUMBER AND OF THE
INTERNATIONAL FILING DATE**

(PCT Rule 20.5(c))

		Date of mailing (day/month/year)	04 Mar 2005
Applicant's or agent's file reference 14853-2PCT		IMPORTANT NOTIFICATION	
International application No. PCT/US2005/000508	International filing date (day/month/year) 07 Jan 2005	Priority date (day/month/year) 09 Jan 2004	
Applicant THE CATHETER EXCHANGE, INC.			
Title of the invention DRAIN WITH OCCLUSION REMOVING STRUCTURE			

1. The applicant is hereby notified that the international application has been accorded the international application number and the international filing date indicated above.

2. The applicant is further notified that the record copy of the international application:

was transmitted to the International Bureau on _____ 04 Mar 2005

has not yet been transmitted to the International Bureau for the reason indicated below and a copy of this notification has been sent to the International Bureau*:

because the necessary national security clearance has not yet been obtained.

because (reason to be specified): _____

* The International Bureau monitors the transmittal of the record copy by the receiving Office and will notify the applicant (with Form PCT/IB/301) of its receipt. Should the record copy not have been received by the expiration of 14 months from the priority date, the International Bureau will notify the applicant (Rule 22.1(c)).

3. FOREIGN TRANSMITTAL LICENSE INFORMATION	Completed by: RD _____
<input type="checkbox"/> Additional license for foreign transmittal not required. This subject matter is covered by a license already granted or the equivalent U.S. national application. Refer to that license for information concerning its scope.	
<input type="checkbox"/> License for foreign transmittal not required. 37 CFR 5.11(e)(1) or 37 CFR 5.11(e)(2). However, a license may be required for additional subject matter. See 37 CFR 5.15(b).	
<input checked="" type="checkbox"/> Foreign transmittal license granted. 35 U.S.C. 184; 37 CFR 5.11 on _____ 01 Mar 2005 <input checked="" type="checkbox"/> 37 CFR 5.15(a) <input type="checkbox"/> 37 CFR 5.15(b)	(date)

Name and mailing address of the receiving Office
 Mail Stop PCT, Commissioner for Patents
 P.O. Box 1450, Alexandria, VA 22313-1450
 Facsimile No. 703-305-3230

Authorized officer
 Rita Dozier 
 Telephone No. 703-308-9290 EX 119

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:		
DAVID A. FARAH SHELDON & MAK PC 225 SOUTH LAKE AVENUE SUITE 900 PASADENA, CALIFORNIA 91101		

**NOTIFICATION OF RECEIPT
OF SEARCH COPY**

(PCT Rule 25.1)

Date of mailing (day/month/year)	04 Mar 2005	
Applicant's or agent's file reference 14853-2PCT	IMPORTANT NOTIFICATION	
International application No. PCT/US2005/000508	International filing date (day/month/year) 07 Jan 2005	Priority date (day/month/year) 09 Jan 2004
Applicant THE CATHETER EXCHANGE, INC.		

1. Where the International Searching Authority and the receiving Office are not the same Office:

The applicant is hereby notified that the search copy of the international application was received by this International Searching Authority on the date indicated below.

Where the International Searching Authority and the receiving Office are the same Office:

The applicant is hereby notified that the search copy of the international application was received on the date indicated below.

04 Mar 2005

(date of receipt).

2. The search copy was accompanied by a nucleotide and/or amino acid sequence listing or tables related thereto in computer readable form.

3. Time limit for establishment of international search report and written opinion of the International Searching Authority
The applicant is informed that the time limit for establishing the international search report and the written opinion of the International Searching Authority is three months from the date of receipt indicated above or nine months from the priority date, whichever time limit expires later (Rules 42.1 and 43bis.1(a)).

4. A copy of this notification has been sent to the International Bureau and, where the first sentence of paragraph 1 applies, to the receiving Office.

Name and mailing address of the ISA/ Mail Stop PCT, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 703-305-3230	Authorized officer Rita Dozier  Telephone No. 703-308-9290 EX 119
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TRANSMITTAL LETTER TO THE UNITED STATES RECEIVING OFFICE

Express Mail mailing number:	EV 276872935 US	Date of Deposit:	7 JANUARY 2005
File reference no.:	14853-2PCT	International application no. (if known):	PCT/US 05/00508 to be assigned
Title of the invention: DRAIN WITH OCCLUSION REMOVING STRUCTURE			
Earliest priority date claimed (Day/Month/Year):		9 JANUARY 2004	

This is a new International Application

SCREENING DISCLOSURE INFORMATION:

In order to assist in screening the accompanying international application for purposes of determining whether a license for foreign transmittal should and could be granted and for other purposes, the following information is supplied. (check as many boxes as apply):

- The invention disclosed was **not** made in the United States of America.
- There is no prior U.S. application relating to this invention.
- The following prior U.S. application(s) contain subject matter which is related to the invention disclosed in the attached international application. (*NOTE: priority to these applications may or may not be claimed on the Request (form PCT/RO/101) and this listing does not constitute a claim for priority*).

application no.	60/535,224	filed on	9 January 2004
application no.	60/563,597	filed on	19 April 2004

The present international application contains additional subject matter not found in the prior U.S. applications(s) identified above. The additional subject matter is found on pages **THROUGHOUT** and **DOES NOT ALTER** **MIGHT BE CONSIDERED TO ALTER** the general nature of the invention in a manner which would require the U.S. application to have been made available for inspection by the appropriate defense agencies under 35 U.S.C. 181 and 37 CFR 5.15.

Itemized list of contents

Sheets of Request form:	4	Check no.:	PAID BY DEPOSIT ACCOUNT	
Sheets of description (excluding sequence listing):	22	Return receipt postcard:	1	
Sheets of claims:	6	Power of attorney:	2	
Sheets of abstract:	1	Certified copy of priority document (specify):	N/A	
Sheets of drawings:	8	Other (specify):	EXPRESS MAIL CERTIFICATE	
Sheets of sequence listing:	N/A			
Sequence listing diskette/CD:	N/A			
Tables related to sequence listing CD:				

The person signing this form is:	<input type="checkbox"/> Applicant	David A. FARAH, M.D.
	<input checked="" type="checkbox"/> Attorney/Agent (Reg. No.) 38,134	Name of person signing
	<input type="checkbox"/> Common Representative	Signature <i>David Farah</i>

This collection of information is required by 37 CFR 1.10 and 1.412. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

New International Application
Inventory of Unscannable or Missing
Items

Serial Number PCT/US 05/00508

Check This Column if Item is Present	Item	Check this column if Item is Missing on Filing
	Return Receipt Postcard	
	Check amount \$ _____	<input checked="" type="checkbox"/>
	DNA Diskette	
<input checked="" type="checkbox"/>	PCT EASY Diskette	
<input checked="" type="checkbox"/>	Express Mail Label or Envelope	
	Other (specify)	
	Cover Letter	

UNITED STATES RECEIVING OFFICE(RO/US) FEE CODING AND RECORDING SHEET

 ADD'L SHEETS

IDENTIFICATION OF THE INTERNATIONAL APPLICATION

INTERNATIONAL APPLICATION NUMBER

INTERNATIONAL FILING DATE

APPLICANT (Name)

PAYMENTS				REFUNDS	
Payment on Filing		Deposit Account	Deposit Account	To Deposit Account	To Deposit Account
Deposit Account		DATE:	DATE:	DATE:	DATE:
<input type="checkbox"/> CASH/CHECK	[REDACTED]	<input type="checkbox"/> CASH/CHECK	<input type="checkbox"/> CASH/CHECK	<input type="checkbox"/> BY CHECK	<input type="checkbox"/> BY CHECK
150				159	
151					
153					
800					
..					
801					
802					
899	Total Paid:	Total Paid:	Total Paid:	Total Refunded:	Total Refunded:
566					
159					
States included for 892:		892:	892:		
States included for 893:		893:	893:		

01/14/2005 MKAYPAGH 00000004 192090 PCT/US05/00508

01 FC:1501 300.00 DA
 02 FC:1502 1000.00 DA
 03 FC:1701 1053.00 DA
 04 FC:1703 132.00 DA
 05 FC:8007 40.00 DA

| RO/US Authorization |
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